Technical and functional dimensions in reconstructive middle ear surgery

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TECHNICAL AND FUNCTIONAL DIMENSIONS IN RECONSTRUCTIVE MIDDLE EAR SURGERY

A.G.W. KORSTEN-MEIJER

Stellingen

behorende bij het proefschrift

Technical and Functional Dimensions in Reconstructive Middle Ear Surgery

Astrid Korsten-Meijer
Groningen, 19 februari 2003.

Slechthorendheid bij politici neemt significant af in de tijd voorafgaande aan de verkiezingen en neemt spontaan weer toe in de daaropvolgende regeringsperiode.

De slechtste beslissing in de politiek is het niet nemen van een besluit.

Zowel protrusie als extrusie van middenoorimplantaten van hydroxylapatiet wordt grotendeels voorkomen door het aanbrengen van een kraakbeenschijfje tussen het trommelvlies en de prothese (dit proefschrift).

Ook een vragenlijst met adequate psychometrische eigenschappen heeft zijn beperkingen, wanneer de lijst wordt gebruikt om het resultaat te meten van medische interventie in een individuele patiënt (dit proefschrift).

Eén publicatie maakt nog geen proefschrift.

Een arts behandelt, de natuur is mild.

Elke mens is een kleine wereld.

Een sociaal acceptabel gehoor wordt niet gedefinieerd door een maximaal verlies uitgedrukt in decibellen (dit proefschrift).

In het algemeen geldt: hoe ernstiger het gehoorsverlies gemeten in dB HL, hoe slechter de score op een vragenlijst die zich specifiek richt op de gehoorkwaliteit, zoals een individu die in het dagelijks leven ervaart (dit proefschrift).

Wie stopt met beter worden, houdt op met goed zijn.

Alleen al vanwege de toevalsvariatie is de kans groot dat onderzoekingen elkaar tegenspreken.

De inhoud van gesprekken die gevoerd worden met een mobiele telefoon bevestigt het vermoeden dat mobiel bellen wel degelijk schadelijk is voor de hersenen.

Het is onterecht dat vele gemeentes en gemeentelijke instellingen het verbouwen van oude woningen en boerderijen als zorgelijk beschouwen.

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Voor Jac en Matthijs

Voor mijn ouders

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Chapter 1

General introduction

General introducion

Since the second half of the past century the fundamental techniques and concepts of reconstructive middle ear surgery to restore or conserve hearing have been subject of debate and extensive scientific interest. In general, the reconstruction of the tympanic membrane and the ossicular chain as part of a tympanoplasty operation must be regarded as an elective otological intervention with the aim to reduce the disability of the patient without complicating side-effects. The success or failure of a middle ear reconstruction procedure is mainly determined by two different entities: the technical dimension and the functional dimension.

Technical dimension

From the early beginning of reconstructive middle ear surgery attention is focused on the technical aspects: the evolution of microsurgical techniques, the importance of eustachian tube function, grafts used for the reconstruction of the tympanic membrane and the ossicular chain and the introduction of biomaterials for implantation purposes. The first synthetic implant materials were constructed of plastic material. Later the ceramics, and in particular the calcium phosphate ceramics were introduced because of their bioinertness, bioactivity and biocompatibility (1-8). The plastic implant materials showed intrinsic problems of rejection and extrusion as the result of a foreign body reaction to the material. However, with the introduction of the highly biocompatible calcium phosphate ceramics, rejection is seldom observed anymore. Extrusion of the ceramic middle ear implants is still observed when the implant is in direct contact with the tympanic membrane, which is probably not caused by a foreign body reaction to the implant but by pressure necrosis of the tympanic membrane (9-13).

Functional dimension

Since recent years scientific and clinical interest is increasing to assess the disability or handicap experienced by an individual due to hearing impairment. This assessment is not only important for clinical management and rehabilitation purposes, but is also relevant with regard to employment and medico-legal related issues. There are a few ways to assess hearing after reconstructive middle ear surgery. It can be measured either by performance testing or in terms of self-report (14-24). Various investigators demonstrated that pure-tone audiometry alone is a moderate predictor of subjective difficulty experienced in daily life listening. In obtaining insight into the hearing quality of hearing impaired people, self-assessment measures of hear-

ing ability along with performance measures can be used (14-24). In this thesis we used the Amsterdam Inventory for Auditory Disability and Handicap (AIAD) (14) as a self-report inventory beside pure-tone thresholds in dB HL to assess individual hearing function.

Objectives of this thesis

In this thesis the first part is concentrated on a highly relevant issue of the technical dimension in reconstructive middle ear surgery: the aspects of biocompatibility of synthetic middle ear implants.
The second part of the thesis is focused on the functional dimension in reconstructive middle ear surgery: the assessment of the hearing (dis)ability in the normal and hearing impaired individual.

In Chapter 2 a historical and contemporary review of the literature concerning reconstructive middle ear surgery is described. Special attention is paid to middle ear mechanics, implant materials, cartilage interposition and assessment of hearing function.

In Chapter 3 a prospective animal experimental study is presented. A cartilage disc is interposed between a synthetic middle ear prosthesis and the tympanic membrane in guinea pigs to investigate the effect of cartilage interposition on the protrusion and extrusion process of a synthetic implant.

In Chapter 4 we describe a standard method of producing a cartilage disc, that is thin enough not to interfere with the mechanical properties of the sound-conducting mechanism, yet thick enough to prevent extrusion of a synthetic middle ear prosthesis, when interposed between a synthetic middle ear prosthesis and the tympanic membrane.

In Chapter 5 we investigate the biocompatibility of hydroxylapatite-polyethylene composite implants (HAPEX, Entermed). The histopathological aspects of clinically retrieved prostheses were studied by light microscopy, transmission electron microscopy and scanning electron microscopy.

In Chapter 6 we perform an explorative survey on the psychometric aspects concerning assessment of hearing disability. Aim of this study is to define further parameters for a future study on this issue.

In Chapter 7 the psychometric adequacy of a self-report inventory for hearing: the (modified) Amsterdam Inventory for Auditory Disability and Handicap (AIAD) is

investigated. The psychometric adequacy of the (modified) AIAD is determined by measuring its reliability and validity. The reliability is tested by measuring internal consistency, split-half correlation and test-retest reproducibility, also factor analysis is performed. The validity is tested by measuring construct and criterion validity.

In Chapter 8 the test-retest distributions and the interval for true score change of the (modified) Amsterdam Inventory for Auditory Disability and Handicap are investigated, when the latter is used to measure the individual effect of surgical intervention.

In Chapter 9 the relation between objective and subjective measures of hearing by means of audiometry and psychometry after reconstructive middle ear surgery is evaluated.

In Chapter 10 the results of this study are summarized and conclusions are presented.

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Chapter 2

Reconstructive middle ear surgery: a review of the literature

DEFINITIONS

Reconstructive middle ear surgery
An operation performed to restore the middle ear function including the reconstruction of the ossicular chain and/or the tympanic membrane.

Tympanoplasty
An operation performed to eradicate disease in the middle ear and to reconstruct the hearing mechanism, without mastoid surgery, with or without tympanic membrane grafting (Committee on Conservation of Hearing of the American Academy of Ophthalmology and Otolaryngology, 1965).

Ossiculoplasty
An operation performed to repair or reconstruct the middle ear ossicular chain using transplant or implant material.

Transplantation
The transfer of living tissue or an organ, and insertion in another part of the body or in another body.

Implantation
The insertion of grafting material, not originating from vital or non-vital cells, tissue or organism.

Autogeneic
Tissue transplanted from one part of the body to another in the same individual.

Isogeneic
Tissue transplanted between genetically identical individuals.

Allogeneic
Tissue transplanted between genetically non-identical members of the same species.

Xenogeneic
Tissue transplantation between members of different species.

Historical aspects

Until the late eighteenth century, middle ear and mastoid operations were only performed to evacuate pus from the middle ear and mastoid, when there were symptoms threatening to life. In the end of the eighteenth century, Baron Bergen, personal physician to the King of Denmark, persuaded a surgical colleague to operate on his mastoid process to relieve deafness and tinnitus. It is not surprising that this operation, undertaken in a clean field before any knowledge of surgical asepsis, ended in infection. When Bergen died 12 days later in great pain from the mastoid operation based on mistaken indications, the procedure fell into a disrepute that lasted nearly 100 years (1).

The first surgical reconstruction procedure of the middle ear was the stapes mobilization of Kessel in 1878, soon followed by Berthold's plastic repair of a perforated tympanic membrane in the same year, and Kiesselbach's attempt in 1883 to correct a congenital meatal atresia (1). However, despite the successes the new surgery of deafness declined and almost died out because there were a few reports of serious infections following the early operations. Reasons for the opposition toward reconstructive surgery of the middle ear were the imperfect development of sterile technique and the absence of protective antibiotic preparations, with the danger and the fear of infecting a clean field in the mastoid process and labyrinth. An additional reason for the skepticism toward operation to improve hearing may have been the lack of audiometers for quantitative measurements of hearing before and after surgery.

Picture 1. Nylen

The development of the operating microscope, first by Nylen in 1921 (Picture 1), who used a monocular instrument, and then by Holmgren, who introduced a the binocular operating microscope in 1922, was an important advance designed to play an increasing role in the perfection of fenestration, stapes, and tympanoplastic surgery (1,2). Holmgren began his long series of operations on the middle ear for otosclerosis, demonstrating that with modern methods of aseptic technique, the non-infected mastoid process and labyrinth could after all, be opened safely. The real turning point in the reorientation of otologic surgery away from operations for infection toward reconstruction of the hearing mechanism occurred with the introduction of the antibiotics in 1935. At this time sulfonamide therapy of acute otitis media and otologic complications had begun to lessen the urgency and frequency of operations for acute mastoiditis. With the later addition to sulfonamides of penicillin, post-operative infections lost much of their threat.

The subsequent development of middle ear reconstruction techniques has gone through major changes (1,2). The two basic principles of middle ear reconstruction

were defined in 1950 by Davis and Walsh, namely, sound pressure transformation for the oval window and sound protection for the round window. The modern term tympanoplasty was first used in 1953 by Wullstein (Picture 2), to describe surgical reconstruction of the middle ear hearing mechanism that had been impaired or destroyed by suppurative disease. These operations are designed to improve hearing in various types and degrees of middle ear lesions. Over the years, definitions and classifications of tympanoplasty have been proposed by various workers. The original classification of tympanoplasty by Wullstein as described here is still commonly used (2). Tympanoplasty type 1: myringoplasty with restoration of the normal middle ear; Tympanoplasty type 2: the ossicular chain is partially destroyed but preserved and continuity has been restored; Tympanoplasty type 3: myringostapedopexy, producing a shallow middle ear and a columella effect; Tympanoplasty type 4: round window protection with a small middle ear, a mobile footplate is left exposed; Tympanoplasty type 5: closed middle ear with round window protection; fenestration in the horizontal semicircular canal covered by a skin graft.

Picture 2. Wullstein

In 1956 the first stapedectomy was performed by Shea (Picture 3)(2). He closed the oval window after extraction of the stapes with a thin slice of connective tissue and inserted a prosthesis from incus to oval window to restore the normal mechanics of the middle ear. Many modifications of Shea`s stapedectomy have been designed and employed, all following the principles firmly established by Shea that the oval window needs to be sealed, and that there must be ossicular continuity. Hall and Rytzner performed in 1957 the first ossicular chain reconstruction using autogenous ossicular bone (1,2). In the early 1960's autogenous and allogen ossicles have been popular for ossicular reconstruction in tympanoplasty. In the years following, the autogenous ossicular replacement prostheses were abandoned because of the possible risk of persistence of infectious disease or cholesteatoma in the transplantation material. The allogen ossicular replacement prostheses were abandoned because of the possible risk of transmission of AIDS and slow virus diseases as Creutzfeldt-Jacob Disease (1,2). In the last decades a large number of new, synthetic implant materials for middle ear reconstruction have been introduced (1,2). These implants have been designed in many prosthetic forms. The first materials were the plastics, but these new materials showed in longer postoperative periods a high incidence of extrusion. In later years different types of ceramics were introduced. Of the ceramics, hydroxylapatite has the closest resemblance to the mineral matrix of human bone. Because of

Picture 3. Shea

this resemblance it seemed promising for use as a bone substitute in otologic surgery. Hydroxylapatite has become the most widely used of any prosthetic materials ever manufactured for ossicular repair because of it's biocompatibility, bioactivity and bioinertness.

TECHNICAL DIMENSIONS

Middle ear mechanics and physiology in relation to tympanoplasty

By means of a rather large hydraulic ratio of a large tympanic membrane acting on a small stapes footplate, combined with a rather small lever ratio of the longer handle of the malleus acting on the slightly shorter long process of the incus, air-borne sound vibrations of large amplitude but small force are transformed to fluid-borne sound vibrations of small amplitude but large force. Today von Békésy's calculations of the effective vibrating surface of tympanic membrane area compared with the stapes footplate area of 17 to 1 and lever effect of the ossicular chain of 1.3 to 1 are generally accepted. The 17 hydraulic ratio times the 1.3 lever ratio yields a total increase of pressure of the oval window of 22 times. This is termed the sound-pressure-transformer ratio of the normal human ear.

The round window in the normal ear acts as a relief opening at the opposite end of the cochlear duct from the stapes footplate to permit maximum to and from vibratory movements of the relatively noncompressible cochlear fluid column in the rigid bony cochlea. In the intact ear, the round window membrane movements are largely passive in response to the stapes footplate movements, because the intact tympanic membrane protects the round window from competitive sounds, partly by damping and partly by a phase lag, so that what little sound does reach the round window may actually strengthen rather than cancel the movements of the cochlear fluid column. Sound can be conducted into the cochlea by two distinct mechanisms, named ossicular coupling and acoustic coupling (3,4). Ossicular coupling occurs by the way of the tympanic membrane and the ossicles and results in an increase of sound pressure applied to the stapes compared to the sound pressure in the ear canal. At the same time, movement of the tympanic membrane also creates a sound pressure in the middle ear cavity. Because the sound pressure that acts on the oval and round window are not identical, the difference in sound pressure on the oval and round window is termed acoustic coupling. Ossicular coupling and acoustic coupling result both in motion of the stapes. The cochlea responds to the difference in sound pressure between the cochlear windows. Acoustic coupling is about 60 dB smaller than ossicular coupling. Therefore ossicular interruption results in a conductive loss of about 60 dB.

A perforation in the tympanic membrane removes sound protection from the round window, with a tendency for sound reach both windows at nearly the same time, thus canceling the resultant movements of the cochlear fluid column. The canceling effect of sound on the unprotected round window rises rapidly until with a total

perforation there is a loss of 40-45 dB. An interruption of the ossicular chain behind an intact tympanic membrane produces an enormous and maximum loss of hearing of the conductive type because now both windows lie behind sound protection and there is no sound-pressure transformation for the oval window.
This situation give s a hearing loss of maximum 60-65 dB. The ideal tympanoplasty restores sound protection for the round window by constructing a closed air-containing middle ear against the round window membrane and restores sound pressure transformation for the oval window by connecting a large tympanic membrane or substitute membrane with the stapes footplate via either an intact or a reconstructed ossicular chain. To accomplish the two physiologic principles of tympanoplasty, sound protection for the round window must be first provided by means of a tissue graft to repair the tympanic membrane defect, and the middle ear must be lined with mucosa and must contain air to the protected window. Then sound pressure transformation for the oval window must be provided by large mobile ossicular continuity between the large tympanic membrane and small oval window.
In general the hearing results after tympanoplasty will depend on the adequacy of the middle ear aeration, the efficacy of the reconstructed tympanic membrane and the efficacy of the reconstructed ossicular chain (3,5,6). Mechanics to the ossicular reconstruction include stiffness and mass of the prosthesis, it's position, tension, length and coupling. In general, the stiffness of an ossicle strut will not be a significant factor as long as the strut stiffness is much greater than that of the stapes cochlear impedance. Middle ear sound transmission should not be significantly affected by substantial increases in ossicular mass. The mass of an ossicular replacement prosthesis can be 16 times greater than that of the stapes with little effect on the hearing results (3,5). Regarding the position of the prosthesis in relation to the tympanic membrane, the tympanic membrane couples sound to the manubrium so intuitive it makes sense to place the prosthesis at the manubrium (3,7). With unfavorable anatomy it is sometimes more stable to place the prosthesis from the stapes head to the postero-superior quadrant of the tympanic membrane (3,8). Experimental temporal bone data suggest that positioning a prosthesis to the tympanic membrane gives acceptable results, provided that the diameter of the prosthesis in contact with the tympanic membrane is at least 3-4 mm. An ossicular prosthesis should not be too long: that causes undue tension within the tympanic membrane and annular ligament and will lead to a significant air-bone gap (3,7). Coupling refers to how well the motion of the footplate follows the motion of the prosthesis and the tympanic membrane. A prosthesis will only transmit sound effectively if there is good coupling at both ends. This is an important cause of a persistent air-bone gap. (3,7). For malleus to stapes suprastructure reconstruction it is seen that tilting of the footplate can be quite considerable. Tilting is determined by a sidewards motion of the stapes suprastructure. This tilting is minimized when the prosthesis is positioned as much as possible along the axis. Human

temporal bone measurements have also indicated that the angle between the stapes and a prosthesis should be less than 45 degrees for optimal sound transmission above which too much energy is lost due to tilting of the footplate (3,7).

Transplant and implant materials

Transplant materials

In sharp contrast to otologic surgery prior to the use or advent of antibiotics, which was almost exclusively concerned with the evacuation of pus from the temporal bone, the majority of all operations on the ear today are undertaken in a clean field. Fortunately today with a clear understanding of the pathology of the various types of middle ear infection, a clear cut and sharp distinction can be made between infections controllable by antibacterial medications and those for which, because of their particular features, surgery alone can be effective. Hall and Rytzner performed in 1957 the first ossicular chain reconstruction using autogenous ossicular bone. Jongkees challenged the usefulness of autogenous ossicular bone grafts because of failure to control the infection in chronic suppurative otitis media. It might be due to occult osteitis in the ossicles retained in the middle ear after the surgical removal of mucosal disease and or cholesteatoma. These suspicions were confirmed when Grippaudo in 1958 reported histological evidence of infection in 92% of incudes and mallei removed from 42 cases of chronic suppurative otitis media. Similar evidence of osteitis in removed ossicles was reported by Belluci and Wolff in 1966 and Steinbach and Hildeman in 1972. Realizing to find a new material to reconstruct the ossicular chain in patients missing one or more middle ear ossicles the allogen implant materials were introduced. They were preserved in 70% ethyl alcohol prior to use. Studies of Austin in 1971 and Kerr and Smith in 1971 showed that there was no evidence of allogen ossicular bone rejection in the middle ear and that in time the grafts would be incorporated into the ossicular chain as vital structures, although complete replacement of the grafts by new bone would be rare. Preservation of cadaver ossicular bone by autoclaving was introduced by Hildyard in 1967. He found no immune or inflammatory responses. Recently otologic surgeons are becoming reluctant to use allogen donor materials because of the risk of transmission of AIDS and slow virus diseases as Creutzfeldt-Jacob Disease. Till now no patients are described with the transmission of AIDS. Meanwhile three articles have been published with the possible transmission of the CJD-prion by using Lyodura (9) and pericard (10,11). Majoor 1993 (12) concluded that the use of allogen middle ear transplants is only justified after application of careful donorselection and specific and adequate conservation methods. In our clinic however, we abandoned allogen middle ear transplants because of the above mentioned alarming reports and excellent alternatives with high cost-effectiveness compared to the time-consuming processing of transplant

material. In our department synthetic implants are exclusively used instead of transplantation material.

Implant materials

In the recent years various types of new synthetic materials were specially designed for implantation in the middle ear (2,13). These implants were designed to have the same characteristics and function of the homografts. The synthetic materials for tympanoplasty can be divided in three categories: metals, plastics and ceramics (2,13,14,16,17,18). The metals (stainless steel and others), although well tolerated in otosclerosis surgery, demonstrated high extrusion rates, especially in ears with a history of chronic otitis media. Three porous plastic materials, namely Proplast, Plastipore and Polycel, have been developed for use in tympanoplasty and mastoidectomy. Proplast was firstly used in 1975, but resulted in foreign body reactions to the prostheses and extrusion of these prostheses through the tympanic membrane. Plastipore and Proplast reported to have non-reactive properties and sufficient porosity to encourage host tissue ingrowth to stabilize the implant material in the middle ear. However, extrusion occurred in high percentages. There was also light and electron microscopic evidence that biodegradation of Plastipore and Proplast occurred in the middle ear and the prosthesis evoked local but sustained foreign body reactions. The most recent materials available for ossiculoplasty are the ceramics (2,12,14,15,19-23). The ceramics include aluminium oxide and the calcium phosphates. The calcium phosphates ceramics are particularly attractive for ossicular chain reconstruction because they belong to the most biocompatible materials available today, besides they are highly bioactive and bioinert (12,15,19,21,24,25). Bioinert implants are materials that do not release detectable trace substances. Bioactive implants are materials that react favorable with the body tissue`s to promote soft tissue attachment. This attachment is a direct chemical bond to the surface of the material, not merely a mechanical attachment. The use of bioactive glass-ceramics was declined for middle ear surgery because of their difficulty in trimming the glass prostheses, their tendency of extrusion, and their instability in infected environments (14). Hydroxylapatite ceramic is a rigid dense calcium phosphate ceramic that conducts vibratory energy quite efficiently. Hydroxylapatite is the essential mineral matrix of bone and is characterized by a stochoimetry of CA10(PO4)6(OH)2 (2,14,15,19,21-23). Several bioceramics are classified as calcium phosphates, but only hydroxylapatite ceramic has the identical calcium-to-phosphate ratio of natural bone mineral. The implants in the middle ear become covered by a well-vascularized mucous membrane with no clinical signs of inflammation. Initial experiments showed that a large proportion of the calcium phosphate implant was covered by an epithelial layer within the first two weeks. As implantation time increased, the implant gradually became completely covered by this epithelial layer, in which all cell types characteristic for the middle ear could be distinguished suggesting good

biocompatibility of hydroxylapatite (19,21-23,26-28). Unlike the plastic and metal prostheses, hydroxylapatite has demonstrated superior tolerance in the presence of acute infection or eustachian tube dysfunction. (21,28,29). Grote was the first to report the clinical use of hydroxylapatite in middle ear reconstruction, and has reported excellent long term hearing results. After him, others have also reported good short and long term hearing results.
However, hydroxylapatite is technically difficult to use intraoperatively, it is brittle and shatters easily when drilled or trimmed with sharp instruments (29). Because hydroxylapatite was needed only against the tympanic membrane, combining the hydroxylapatite head with another, more easily trimmable material for the shaft, seemed the next logical development (14). In order to make the hydroxylapatite implant more easy to use intraoperatively, polyethylene was considered as an additional material. Polyethylene is easy to trim and to use intraoperatively. Polyethylene behaves as a biocompatible material in the middle ear however, when in contact with the tympanic membrane, the material becomes surrounded by macrophages and foreign body giant cells representing rejection. To combine the properties of biocompatibility and manipulation, a homogeneous material consisting of 40 % hydroxylapatite and 60 % polyethylene was introduced (HAPEX, Smith and Nephew) (30). This composition results in a biocompatible material reflecting the mechanical properties of cortical bone, yet is soft enough to cut with a knife. The HAPEX middle ear prostheses consist of a hydroxylapatite head and a hydroxylapatite-polyethylene shaft. Hearing results with hydroxylapatite prostheses with a HAPEX shaft are comparable to results obtained with hydroxylapatite alone (29). Further research to the biocompatibility of hydroxylapatite-polyethylene composites in ossiculoplasty in human is needed, for preference by means of a prospective clinical study.

Prognostic factors

In the beginning of the 1950's the attempts started to reconstruct the defect ossicular chain in tympanoplasty. During the last 40 years, various surgical techniques and materials have been proposed and applied in an attempt to reconstruct the conductive mechanism of hearing depending on the type and extend of damage to the tympanic membrane and the ossicles (31). To be successful, material used for tympanoplasty must possess several characteristics. First it must establish a secure but freely mobile connection between the tympanic membrane and the inner ear fluids, this requires a relatively stiff material that can be placed under tension, in contact with the tympanic membrane but will not extrude. The material must not fix to the surrounding bone of the ear canal or the oval window. It must be well tolerated in the middle ear including long term stability. The mainly important problems with the first synthetic implants were reaction from neighboring tissue, resulting in the development of inflammation, erosion and extrusion of the prostheses.

The following factors are considered to be of prognostic importance with regard to successful middle ear reconstruction (32). A distinction is made between intrinsic and extrinsic factors. The intrinsic factors are criteria related to specific middle ear pathology, including tubal dysfunction and middle ear aeration, quality of the middle ear mucosa (chronic infection) and quality of the tympanic membrane. The extrinsic factors, are directly associated with the implant device and can be differentiated in the biocompatibility of the implant material, implant biomechanics, and anchoring of the implant. The extrinsic factors will be discussed in detail.
The biocompatibility of the implant material is an essential factor. The biocompatible materials have excellent surface properties. They will be covered in a few weeks with mucosa without any foreign body reaction. This in contrast with for example the plastics, where giant cells are seen years after implantation. Implant biomechanics include stiffness and mass, shape, position and length of the prostheses. The basic design of the implant is of importance (for example: non-malleable head versus malleable head, sharp implant edges), also the ease of intra-operative modeling of the prosthesis. The prosthesis should be placed in the best position, with least but optimal tension with a minimum likelihood of dislocation.
Transplants or implants used for ossicular reconstruction should be inserted in a precise position to develop a firm or joint-like connection with the rest of the chain. A pseudoarthrosis-like connection is observed after implantation of ceramic implants. Interposition of cartilage favors the development of such connections with the tympanic membrane. Also important is the medial anchoring of the implant. If the stapes superstructure is intact, the hollow shaft of an implant can be placed over the head of the stapes for stability. Stabilization of the implant when the stapes suprastructure is absent is difficult. Ceramic columellas show a ligamentous-like connection between the implant and the stapes footplate, but it can not prevent lateralization and extrusion. There is no evidence that an osseous connection can be created between hydroxylapatite, glass ceramic or bioglass columella and the footplate. The continuous movements of the reconstruction probably prevents permanent fixation.

Extrusion of middle ear implants

The term "extrusion"originates from the Latin extrudere, which is translated as to push or thrust out (32). Generally extrusion is interpreted as a rejection phenomenon of the body to non-tolerated materials, before or after complete integration of the implanted material. However, in middle ear surgery extrusion of implants is provoked by a variety of causative factors. Low biocompatibility of synthetic implants can be regarded as an important reason for extrusion. The much higher extrusion rates of plastics compared with bioinert ceramics are mainly due to the lack of biocompatibility of the plastics. Typically the extrusion as a result of bad biocompatibility, starts with crust formation visible on the tympanic membrane. The crust can sometimes be

removed by local application of corticosteroids. When the crust is removed, one edge of the implant is seen through a defect in the tympanic membrane.
Extrusion may also be caused by ischemic necrosis of the tympanic membrane due to pressure (32-37). The highly biocompatible ceramic materials become mainly extruded due to decubital necrosis of the tympanic membrane (32,33,35-39). Observations in former studies on the extrusion process showed that the tympanic membrane was more or less retracted and seemed to envelop the prosthesis without any sign of foreign body reaction (35,40).This indeed suggests that extrusion was not due to lack of biocompatibility but to the intrinsic factors including middle ear quality. When ventilation disturbances lead to retraction of an atrophic tympanic membrane, the edge of the implant may interfere with the nutrition of the overlying tympanic membrane. In such a situation partial extrusion may be observed. Partial extrusion does not always progress and may not interfere with a good functional result for several years.
Extrusion rates can be lowered by interposing a small cartilage disc between a synthetic implant and the tympanic membrane (31-37,41-44). Cartilage has the advantage of being well tolerated by the tympanic membrane. It can be placed under some tension, with a very low risk of extrusion (31). Cartilage also does not firmly affix to the surrounding bone. The earliest studies on the use of the highly inert and biocompatible ceramic implants did not recommend the interposition of cartilage when an implant was in direct contact with the tympanic membrane. The more recent papers, on the contrary, advise the use of cartilage because of the risk of extrusion (33,35,37,43-46). The literature refers to average extrusion rates of biocompatible implants varying from 15-22 %; interposing a cartilage disc reduces extrusion rates to 3-6 %, which are comparable to those of transplants (31,32,33,35,36,37,41). The role of the interface is particular important in cases of eustachian tube insufficiency, because the negative pressure inside the middle ear causes abnormal push of the head of the prosthesis against the tympanic membrane (33-37,46,47). Autologous cartilage seems to provide a good interface material between two systems with different elastic modules.
Even when an implant projects slightly from the tympanic membrane, the danger of decubital necrosis will be counteracted by a cartilage shield as long the cartilage prevents any direct contact between the implant and the eardrum (35). It is equally clear that neither the extrusion of a ceramic implant nor liability to extrusion can be prevented with certainty by the interposition of a cartilage disk.
Various alternatives have been used for interposition purposes between the tympanic membrane and the implant, such as autologous cortical bone pate, a small disk of autologous or homologous tragal or concha cartilage with or without unilateral perichondrium, fascia, vein and perichondrium. Nowadays cartilage with perichondrium covering on one side is the most frequently used interposition technique in

tympanoplasty. Histological examination of cartilage and perichondrium disks showed a delicate lamina of connective tissue that was free of round cell infiltration and foreign body giant cells (35). Although cartilage with adherent perichondrium becomes non-viable, the material can remain functional for extreme long periods (33,37,43,47,48,49). In one case-report a cartilage interposition survived a 13 years interval with a normal appearance (48). Cartilage slices with a thickness of 0.4 or 0.5 mm are regarded as a good compromise between sufficient mechanical stability and low acoustic transfer loss (46). Cartilage interposition does not negatively influence the postoperative hearing results, it sometimes gives slightly better hearing results. The reason for improved hearing result with cartilage interposition, could be that the length of a prosthesis need not be so painstakingly adjusted when the prosthesis will be shielded by cartilage (33,35,36,43).

Reports on extrusion rates have to consider follow-up for at least 5 years. Usually the extrusion rates concerning the same implant materials dealt with by different authors differ considerably, and most reports fail to analyze all important factors. Papers dealing with extrusion rates should at least report the implant material, the type of middle ear pathology, interposition of cartilage or direct contact of the implant with the tympanic membrane and the time of follow-up. Actually there has never been published a study that examined the histopatological aspects of the tympanic membrane in reconstructive middle ear surgery with or without cartilage interposition. Neither a study has been published that reported differences in extrusion-rates of ceramic implants with and without cartilage interposition in reconstructive middle ear surgery.

FUNCTIONAL DIMENSIONS

Evaluation of hearing results

To express the effects of a person's hearing impairment, the term hearing disability is often used. The terms "impairment", "disability" and "handicap" are defined according to the WHO (WHO: International classification of Impairments, Disabilities and Handicaps. Geneva, World Health Organization, 1980) as follows. Impairment: any loss or abnormality of psychological, physiological or anatomical structure or function. Disability: any restriction or lack (resulting from impairment) of ability to perform an activity in the manner or within the range considered normal for a human being. Handicap: a disadvantage for a given individual, resulting from an impairment or a disability, that limits or prevents the fulfillment of a role that is normal (depending on age, sex and social and cultural factors) for that individual. In general disability covers the difficulties experienced in everyday life, and handicap covers the emotional and social consequences of hearing impairment. Therefore, to assess hearing ability after tympanoplasty, it seems most adequate to quantify a person's hearing disability, and not their hearing impairment.

Hearing disability can be measured either by performance testing or in terms of self-report (50-60). The specification of hearing status in terms of pure-tone thresholds has many limitations when describing the overall effect of a hearing impairment. Hitherto, information mainly derived from pure-tone audiometry and sometimes speech audiometry has been used in order to assess the difficulties that hearing impaired people experience in daily life. However, various investigators demonstrated that pure-tone audiometry alone is a poor predictor of subjective difficulty experienced in daily life listening. It is common clinical experience in audiologic and otologic practice that individuals with similar audiometric profiles will both describe and exhibit a wide range of hearing difficulties.

Audiometry

Subjective audiometry including pure-tone and speech audiometry is most commonly used to quantify hearing. In the otological literature, the hearing results of middle ear surgery by means of subjective audiometry are frequently reported by closure of the air-bone gap and improvement of the air-conduction threshold in dB HL of the operated ear. Measuring the post-operative air-bone gap is a reflection of the technical success of the operation. Technical success does not automatically assess wether the patient has actually benefitted and has become normal hearing again (61-66, 68-72). After all, the most effective way to close the air-bone gap is to produce a dead ear. It is more useful to plot the air conduction changes wich are achieved by the reconstruction of the middle ear ossicular chain. Improved air-conduction thresholds in the operated ear reflect lessening of the mono-aural disability. However in most conditions, listening is a binaural condition, with an essential contribution of the contra-lateral ear. Not infrequently the clinician becomes aware of a discrepancy between the postoperative improvement of the audiometric thresholds and the patient's opinion of their hearing capacities. An important but underestimated element in hearing, is that the individual ear apparently only participates in hearing if the function of the individual ear is better than a undefined critical value. This critical value is in the otological literature often defined as 30 dB HL, also named social acceptable hearing (61-66, 68-72). If the ear functions worse than the social acceptable hearing level, than that ear probably does not participate actively in the hearing. The non-operated ear is quite correctly the better hearing ear, therefore the hearing is than only based on the hearing function of the contra-lateral cq non-operated ear. Because the skull does not greatly block the transfer of sound around it, speech arising on the side of the poorer hearing ear will be heard primarily by the better hearing ear unless the hearing is symmetrical. Symmetrical hearing is in the otological literature defined as an inter-aural difference of 10 dB HL or 15 dB HL (61-66, 68-72).

Based on the concept that hearing is a binaural function, in the literature two methods have been described for predicting the patient hearing benefit in reconstructive middle ear surgery: the Rule of Thumb by Smith and Patterson (66) and the Glasgow

Benefit Plot by Browning et al. (62). Both methods consider the contra-lateral ear in their evaluation. According to the Rule of Thumb (66) patient benefit is achieved if the average post-operative air-conduction threshold (for 0.5, 1, 2 and 4 kHz) is 30 dB HL or if the inter-aural difference is reduced to 15 dB HL. The Glasgow Benefit Plot (62) is a graphical device were pre- and post-operative air-conduction thresholds are plotted and patient benefit can be predicted according to the area where the plot lies. The pre- and postoperative air-conduction thresholds in both ears are used to evaluate binaural hearing results. The first step of the Glasgow Benefit Plot is to plot each patients preoperative thresholds on the graph in figure 1, on which the vertical axis represents the mean air-conduction threshold in the ear to be operated on and the horizontal axis represents the mean air-conduction threshold in the non-operated ear. The solid diagonal line indicates identical hearing in the two ears. If a patient's preoperative thresholds fall above that line, the ear to be operated on is the patients poorer-hearing ear. If the threshold fall below the solid diagonal line, the better-hearing ear should be operated on. The vertical height of the thresholds above or below the solid diagonal line indicates the magnitude of the difference between the ears. The two dotted diagonal lines (at 10 dB from the solid diagonal line) enclose the area within a patient's hearing would be classified as being symmetric. If a patient's hearing falls without these dotted lines, it is regarded as asymmetric. Normal hearing is an arbitrary concept, in the plot, 30 dB HL is the cut off level; below that level hearing is considered normal. It is unusual to operate on the better hearing ear or on ears with air-bone conduction thresholds of better than 30 dB HL solely to improve hearing.

A patient's preoperative air-conduction thresholds are likely to fall into one of three main preoperative impairment groups. Group 1: unilateral hearing impairment; asymmetric thresholds, group 2: bilateral hearing impairment; asymmetric thresholds, group 3: bilateral hearing impairment; symmetric thresholds. Following surgery, the hearing in the non-operated ear is assumed to be the same, the hearing in the operated ear will change. Such a change in the hearing will be recorded as a vertical line down the Plot. The potential patient benefit is represented in four different postoperative categories (Figure 2). If the patient with a unilateral hearing loss can be given symmetrical hearing post-operatively then the reduction in auditory disability will obviously be significant (area 1 to area "a"). The patient benefit attained from moving the operated ear in a patient with bilateral hearing loss into the normal range will also be significant (area 2 to area "b"). However for the patient who post-operatively still has bilateral hearing loss, the benefits will be marginal and limited to poor listening situations (areas 2 or 3 to areas "c" or "d") .

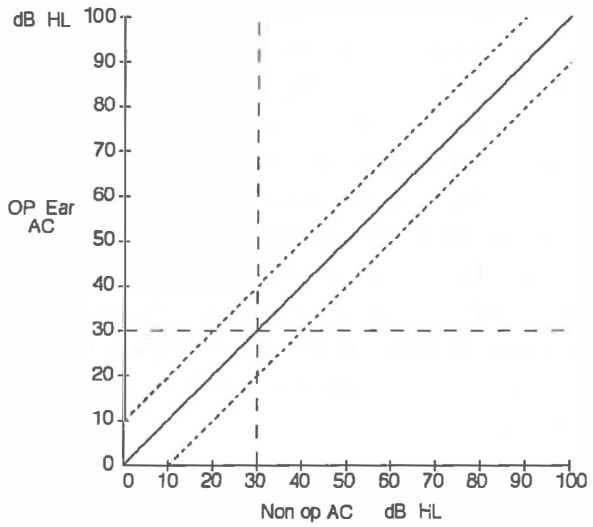

Figure 1. The Glasgow Benefit Plot

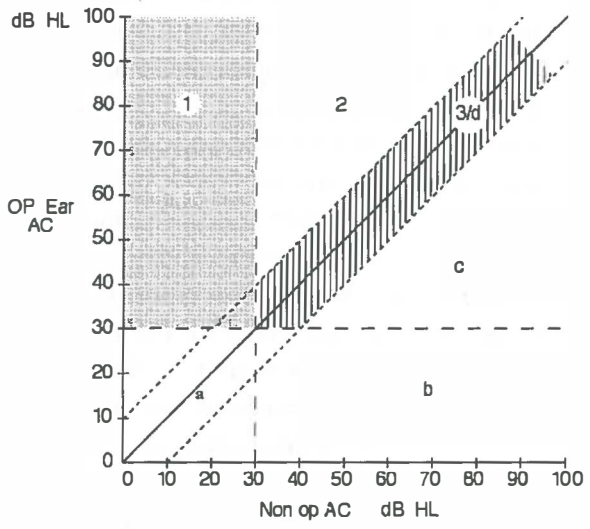

Figure 2. The four different postoperative categories of the Glasgow Benefit Plot represent potential patient benefit

It is important that the Glasgow Benefit Plot system or alternative criteria for patient benefit as advocated by Smyth and Patterson are used. It will prevent too optimistic advice on reconstructive middle ear surgery which is likely to be regarded as unsuccessful in reducing their auditory disability. There are patient categories which are probably unsuitable for purely functional surgery. Normal hearing requires the distribution of information of both cochleas to both auditory cortices, hence advantages of binaural as opposed to mono-aural hearing. Only if an operation can restore more effective auditory function the result will be of benefit to the patient.
However, in the literature the critical value of 30 dB HL as maximum air-conduction threshold for social acceptable hearing is used as arbitrary limit to define normal hearing. Validation of this definition is not only important for clinical management and rehabilitation purposes, but is also relevant with regard to employment and medico-legal related issues.

Self-report inventory

For patients with hearing loss, the ability to communicate effectively depends on sensory and non-sensory factors. General communication skills, acceptance or denial of the hearing loss, overall emotional adjustment, and the behavior and attitude of friends, family and co-workers all can have impact on communication. It is not surprising, that patient performance in typical communication situations is not highly predictable from purely audiometric measures. Audiometric tests do not assess the nonsensory variables that contribute to actual communication performance and their results provide only partial and indirect information about hearing impairment. In describing the overall effect of a hearing impairment, a hearing questionnaire next to performance measures including pure-tone audiometry and speech audiometry is needed to provide a systematic and realistic procedure to quantify the variety of problem areas experienced by a person as a result of their hearing impairment (50-55, 58-60). The advantages of self-report are convenience and external validity. Performance measures are strictly limited to the actual task used in the performance test and do not necessarily measure the effect of loss of hearing and functional behavior. On the other hand, performance testing has the advantage of being able to provide readily reproducible results and is less prone to bias from extraneous factors as exaggeration, personal opinion and inappropriate self-perception. Self-report and performance testing can be viewed as complementary procedures.
To describe the overall effect of a hearing impairment a hearing questionnaire next to subjective audiometry is needed to provide a systematic procedure to quantify the variety of problem areas experienced by persons as a result of their hearing impairment (50-57, 60).

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Chapter 3

Cartilage interposition in ossiculoplasty with hydroxylapatite prostheses: a histopathologic study in the guinea pig

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Introduction

In tympanoplasty, otologic surgeons have successfully used biocompatible synthetic materials to reconstruct the middle ear air conduction system. Synthetic implants are greatly preferred to autografts and allografts (1). At the moment, hydroxylapatite is the most used synthetic material for reconstruction of the ossicular middle ear chain in tympanoplasty. Hydroxylapatite is a calcium phosphate ceramic which resembles the mineral matrix of living bone tissue. It is rapidly covered by epithelial cells and permits differentiation into goblet and ciliated cells without any foreign body reaction. Hydroxylapatite is completely bioactive, biocompatible and osteoconductive (2-5).

There used to be intrinsic problems of rejection and extrusion for all synthetic implants. However, with the introduction of highly biocompatible materials, rejection is seldom observed anymore. Extrusion of a biocompatible ceramic middle ear implant in direct contact with the tympanic membrane is probably not caused by a foreign body reaction but by decubital necrosis of the membrane (6-10). Extrusion rates can be lowered by interposing a small cartilage disc between a synthetic implant and the tympanic membrane (1, 6-15) . Cartilage has the advantage of being well tolerated by the tympanic membrane. It can be placed under some tension, and has a very low risk of extrusion. The literature refers to average extrusion rates of biocompatible implants varying from 15-22 %; interposing a cartilage disc reduces extrusion rates to 3-6%, which are comparable to those of transplants (1, 6-12).

In this study, we implanted hydroxylapatite middle ear prostheses in the bullae of guinea pigs. The guinea pig temporal bone and its contents are similar to those of humans but there are some minor differences. In relation to the temporal bone dimensions the dimensions of the eardrum and the tympanic ring are greater in the guinea pig than in humans, and the tympanic membrane is devoid of the pars flaccida (16).

Two groups of guinea pigs were investigated: the first group consisted of the cases in which a hydroxylapatite prosthesis was directly in contact with the tympanic membrane, the second group consisted of the cases in which a cartilage slice had been inserted between the head of the hydroxylapatite prosthesis and the tympanic membrane. The purpose of this study was to evaluate the histopathological aspects of the tympanic membrane and the differences in extrusion and protrusion between the groups of guinea pigs operated on.

Materials and methods

In this study, middle ear surgery was carried out on 21 female pigmented guinea pigs, weighing about 450 grams. Animal care and use were approved by the Experi-

mental Animal Committee of the University of Groningen, protocol number 1174, in accordance with the principles of the Declaration of Helsinki.

Operation technique

The animals were anaesthetized by an intramuscular injection of Ketalar-Rompun (0.7:0.3). All operations were performed by the same surgeon using a Zeiss stereo microscope. The body temperature was maintained using an electric heating pad. Tympanotomy was performed by the inferior approach (17,18). After stripping off the perichondrium covering, the bulla was opened by creating a square shutter (4 x 4 mm). The prosthesis was custom-made for this experiment. The head of the prosthesis consisted of hydroxylapatite (diameter 2,0 mm), and the shaft was made of a spiral spring which was attached to the prosthesis-head with some dental glue. The prosthesis was implanted between the tympanic membrane and the bulla wall, under minimal tension. The shaft had no contact with middle ear structures other than the bulla wall at its end. In half of the cases, a slice of cartilage with a thickness of 0.3-0.5 mm was interposed between the prosthesis head and the tympanic membrane, with the perichondrium covering opposed to the tympanic membrane. The prostheses including the cartilage disc had approximately the same length as compared to the length of the prostheses without cartilage interposition. The cartilage disc with the overlying perichondrium was obtained from the auricle. After adequate positioning of the prosthesis, the square shutter was replaced on the bulla-defect and fixed with Histoacryl Tissuecol, and wound closure was performed. After six months, the guinea pigs were terminated by decapitation.

Histological processing

After termination by decapitation, the bullae were opened and fixed in 2.5 % glutaraldehyde in 0.1 M sodium cacodylate buffer, pH 7.4. The specimens were then decalcified for five days in 10 % EDTA, pH 7.4, postfixed in 1% OsO_4 with 1% $K_4Ru(CN)_6$ for two to three hours, carefully rinsed in distilled water, dehydrated in a graded ethanol series followed by propylene oxide, and infiltrated using a mixture of 1:1 propylene oxide and Spurr's low viscosity resin for two hours followed by pure resin infiltration overnight. One specimen was embedded in HPMA (hydroxypropyl methacrylate) and stained for elastin. Polymerization took place at 70 C after desiccation in a vacuum. The specimens were cut in semi-thin slices (2 m), and stained with toluidine blue for evaluation by light microscopy (LM). A selection of six pieces were further examined by transmission electron microscopy (TEM). Ultra-thin sections of 100 nm were contrast-stained with 7% uranyl acetate in 70% methanol and lead citrate. Evaluation was performed using a Philips 201 transmission electron microscope operating at 40 kV.

Examination

Before histological processing, in situ inspection of the position, protrusion and extrusion of the prosthesis was performed using a Zeiss stereo operation microscope.
After fixation and embedding, light microscopy (LM) was performed. We studied the histopathological aspects of the tympanic membrane, including signs of protrusion or extrusion of the middle ear prosthesis. Protrusion was defined as prominence of the prosthesis in the tympanic membrane, with the tympanic membrane still intact. Extrusion was defined as prominence of the prosthesis in the tympanic membrane resulting in discontinuity of the tympanic membrane.
In addition to the light microscopical evaluation, we also performed transmission electron microscopy (TEM) evaluations in selected cases. Six cases (5 with cartilage interposition, 1 without cartilage interposition) of apparently normal tympanic membranes as observed with LM were further investigated with TEM. Also three left control ears without intervention were studied by TEM.

Results

We initially implanted hydroxylapatite middle ear prostheses in the right bullae of 21 guinea pigs (11 without cartilage interposition, 10 with cartilage interposition). During the six months follow-up period, three guinea pigs died, two guinea pigs in which cartilage was interpositioned, and one guinea pig without cartilage interposition. There was no clear cause of death. Also two guinea pigs (with cartilage interposition) were excluded after being prepared for evaluation, for technical reasons: in one guinea pig, the prosthesis was situated against the bulla wall and therefore had no contact with the tympanic membrane; in the second one, the fixation and embedding procedure had failed. Consequently, we studied 16 guinea pigs: group A consisted of ten guinea pigs in which the prosthesis was directly in contact with the tympanic membrane, group B consisted of six guinea pigs in which a cartilage disc had been inserted between the head of the prosthesis and the tympanic membrane. Besides the two implantation groups, we studied the histological aspects of a group of six left control ears which had received no intervention.

In situ inspection

Of the 16 right bullae, we observed 15 healthy middle ear cavities without any sign of infection or inflammation. Only one bulla, in which cartilage was positioned in between the prosthesis head and the tympanic membrane, showed a purulent otitis media. Of the 16 bullae, all prostheses were in an adequate position and directly or indirectly in contact with the tympanic membrane, the end of the spiral spring shaft of the prostheses was still in contact with the bulla wall.
We estimated the extrusion and protrusion rates of the prostheses (Table 1): eight cases of extrusion/ protrusion (varying between mild and severe) were observed

(seven without cartilage interposition, one with cartilage interposition). One protrusion/extrusion was questionable (no cartilage interposition) and the resulting seven showed no clear signs of protrusion/extrusion (2 without cartilage interposition, 5 with cartilage interposition). It was impossible to differentiate between extrusion or protrusion.

	In situ inspection	**LM**
no cartilage **n=10**	7 protrusion/extrusion 1 questionable pro-/extrusion 2 normal	3 extrusion 7 protrusion
cartilage **n=6**	1 protrusion/extrusion 5 normal	1 extrusion 1 protrusion 4 normal

Table 1. In situ inspection and LM examination of the tympanic membrane after implantation of hydroxylapatite middle ear prostheses with or without cartilage interposition.

Light Microscopy

Control group (n=6)

We studied six tympanic membranes of left control ears which had received no intervention. The tympanic membrane is built up of three layers: the outer epidermal layer, the middle lamina propria (fibrous layer) and the inner mucous layer, as reported earlier in the literature (19, 20, 21). All the tympanic membranes had an entirely normal appearance without any sign of atrophy. The HPMA-embedded tympanic membrane showed elastin in the epidermal and mucosa layer, but not in the fibrous layer.

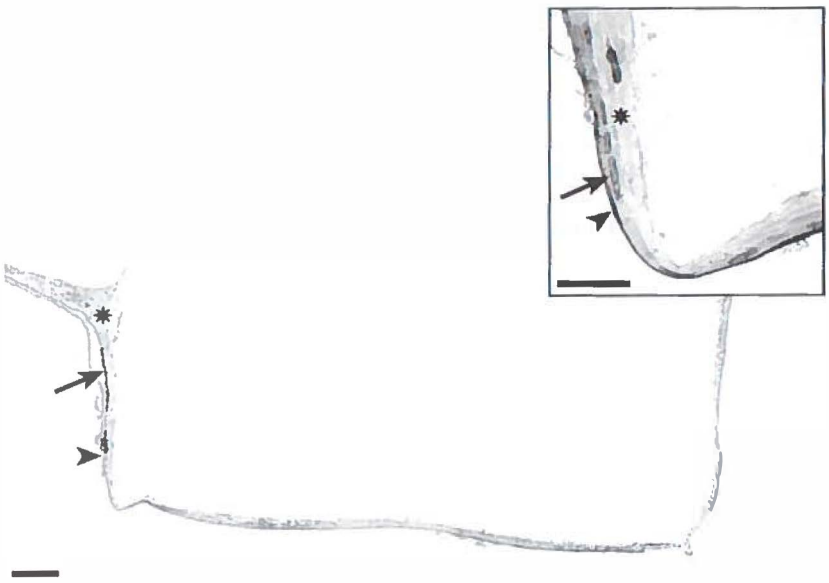

Figure 1. Light microscopy photograph of the tympanic membrane after implantation of a hydroxylapatite middle ear prosthesis without cartilage interposition. The prosthesis protrudes into the tympanic membrane. The middle fibrous layer (arrow) is atrophic with discontinuity at the edge (inset), the outer epidermal layer (arrow head) and the inner mucosal layer (asterisk) are less affected Bar =100μ, bar inset = 20μ

Group A (no cartilage interposition, n=10)

All ears except one showed severe histopathological changes of the tympanic membrane (Figure 1). The most prominent changes took place in the middle fibrous layer. The outer epidermal layer was less affected. Of all ten prostheses, three prostheses were actually extruded, all the remaining protruded (Table 1). The changes in the middle fibrous layer consisted of mild to severe reduction in thickness (atrophy) and discontinuity of the middle fibrous tissue layer to total absence of this tissue layer. The middle fibrous layer of the tympanic membrane was questionably atrophic in one, atrophic in five, and absent in four cases (Table 2).

	LM	TEM
no cartilage	4 absent	
n=10	5 atrophic	
	1 questionable atrophy →	1 with continuous fibers
cartilage	1 absent	
n=6	1 questionable atrophy→	1 with continuous fibers
	4 normal →	3 with fiber intermissions
	→	1 with continuous fibers

Table 2. LM and TEM examination of the tympanic membrane after implantation of hydroxylapatite middle ear prostheses with or without cartilage interposition, with emphasis on the middle fibrous layer of the tympanic membrane.

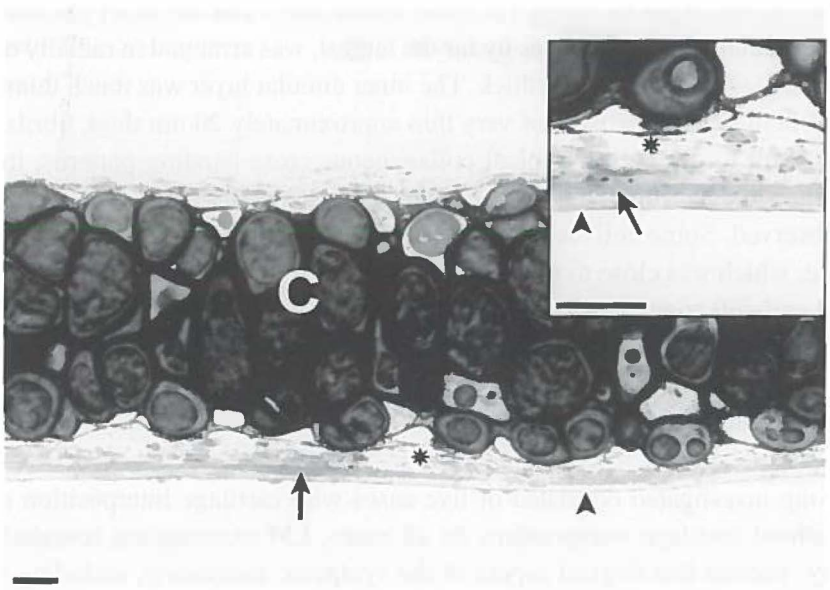

Figure 2. Light microscopy photograph of the tympanic membrane after implantation of a hydroxylapatite middle ear prosthesis with cartilage interposition (C). There are no signs of protrusion or extrusion of the prosthesis. No sign of atrophy of the middle fibrous layer (arrow) is observed. Neither the outer epidermal layer (arrow head) nor the inner mucosal layer (asterisk) are affected. Bar = 20μ, bar inset = 20μ.

Group B (cartilage interposition, n=6)

Histopathological examination of the six animals showed one case of extrusion, in the guinea pig with the purulent otitis media. In only one guinea pig did we observe protrusion of the prosthesis and a tympanic membrane with questionable atrophy of the middle fibrous layer (Table 1 and Table 2). The remaining tympanic membranes were all normal without any sign of atrophy, protrusion or extrusion (Figure 2). The interposed cartilage discs showed some signs of degradation but all had an intact extracellular matrix.
The difference in protrusion- and extrusion-rate between group A (no-cartilage) and group B (cartilage interposition) is statistical significant (Chi-square), $p < 0.001$.

Transmission Electron Microscopy

Control group

The tympanic membranes of the three left control ears showed an outer epidermal layer, an inner mucosal layer and a middle fibrous layer (Figure 3). The fibrous layer consisted of two types of fibers: the outer radial fibres and the inner circular fibers. The outer radial layer, which was by far the largest, was arranged in radially orientated fibers and was about 2-3 μm thick. The inner circular layer was much thinner. The fibers of both layers consisted of very thin approximately 20 nm thick fibrils, which did not seem to display the typical collageneous cross banding patterns; this is in accordance to data from the literature (19,20). Few interruptions of the (radial)fibers were observed. Some cells were present in the middle layer between the fibers. In one case, which was close to the malleus, the lamina propria of the epidermal layer showed cell-cell contacts and many small vesicles were present underneath. The radial fibers at that location were loose and many cells were observed in between.

Research group

The group investigated consisted of five cases with cartilage interposition and one case without cartilage interposition. In all cases, LM examination revealed an apparently normal histological aspect of the tympanic membrane, including the two cases with a questionable atrophic fibrous layer. All tympanic membranes showed a normal appearance of the epidermal layer with TEM (Figure 4). The mucosa layer was absent in all cases, and replaced by a connective tissue layer that connected the tympanic membrane with the underlying cartilage or prosthesis. The connective tissue layer contained fibrocytes, and collagen fibers with the characteristic crossband

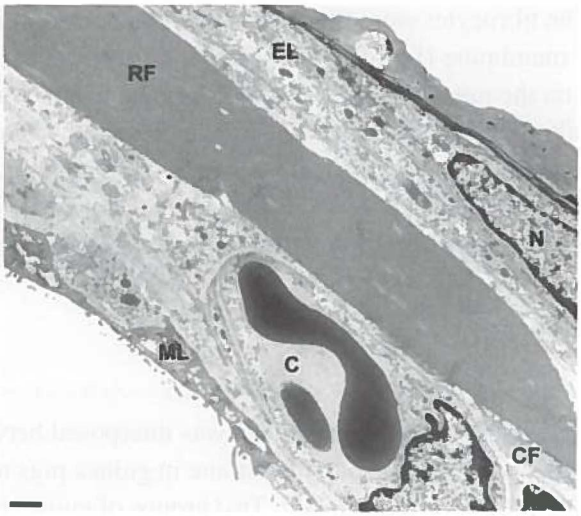

Figure 3. Transmission electron microscopy photograph of the tympanic membrane of a control ear without intervention. The tympanic membrane is built up of the outer epidermal layer (EL), the middle fibrous layer consisting of radial fibers (RF) and smaller circular fibers (CF), and the inner mucosal layer (ML). N= nucleus, C= capillary. Bar = 1μ.

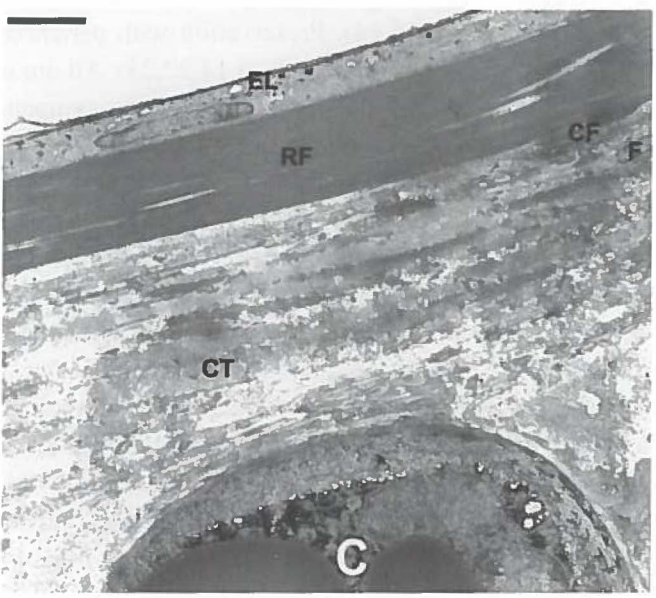

Figure 4. Transmission electron microscopy photograph of the tympanic membrane after implantation of a hydroxylapatite middle ear prosthesis with cartilage interposition (C). The aspect of the outer epidermal layer (EL) is normal. The middle fibrous layer has a normal appearance with the radial fibers (RF) and the smaller circular fibers (CF) still intact. The inner mucosal layer is replaced by connective tissue (CT) containing fibrocytes (F=fibrocyte nucleus) surrounded by collagen. Bar = 5μ.

ing pattern. The fibrocytes were the end result of an active process of remodeling of the tympanic membrane (fibroblasts) which had been stabilized by this point. The basal lamina on the mucosal side was not recognizable anymore in half of the cases, in the other half, it was partly intact. The middle fibrous layer was present in all cases (Table 2). In half of the cases, the fibers were continuous, including the two cases with the questionable atrophy of the fibrous layer with LM. The other half showed some intermissions. Apart from this finding, the histologic appearance of this layer was normal.

Discussion

In this experimental study, a cartilage disc was interposed between a synthetic middle ear prosthesis and the tympanic membrane in guinea pigs to investigate its effect on the extrusion process of the implant. Two groups of guinea pigs were studied: one group with cartilage interposition and one group without cartilage interposition between the implant and the tympanic membrane. A control group was also included.
A synthetic middle ear implant that is shielded by cartilage can easily extrude or become liable to extrude when the cartilage is displaced or resorbed. Clinical and experimental evidence suggests that cartilage alone softens and is either absorbed or replaced by fibrous tissue (6,14). Preservation with perichondrium on one side improves the viability of the cartilage graft (6,14,22,23). All our cartilage discs were covered with perichondrium on the side opposed to the tympanic membrane. Histologic examination of the interposed cartilage discs with a perichondrium covering showed no evidence of resorption. All the interposed cartilage discs had an intact extracellular matrix. It is clear that neither the extrusion of a ceramic implant nor liability to extrusion can be prevented with certainty by interposition of a cartilage disc. The role of the interface is particularly important in cases of relative eustachian tube insufficiency, because the negative pressure inside the middle ear can cause the head of the prosthesis to exert increased pressure against the tympanic membrane (7-9). This may interfere with the nutrition of the overlying tympanic membrane.
The mechanism of extrusion can be infection or inflammation, a foreign body reaction to the prosthesis material or decubital necrosis of the tympanic membrane (6-8). Of all our cases, we reported one case of extrusion as a result of inflammation. The other protrusions/extrusions were not related to an inflammatory process. No lymphocytic infiltration or foreign body giant cells were observed in any cases, suggesting that no foreign body reaction to the hydroxylapatite material was involved. However, the histopathological observations strongly indicated a process of decubital necrosis of the tympanic membrane. The most prominent changes indicating decubital necrosis of the tympanic membrane consisted of atrophy of the middle fibrous layer or total absence of this layer. Abnormal pressure of the prosthesis to

the tympanic membrane may have interfered with the nutrition of the overlying tympanic membrane. Cartilage interposition may have caused less decubital necrosis of the tympanic membrane than a synthetic prosthesis would have done when in direct contact with the tympanic membrane.

Conclusion

In this experimental model, protrusion and extrusion of a hydroxylapatite middle ear prosthesis could be greatly prevented by interposition of a cartilage disc. Higher extrusion/protrusion rates and severe histopathological changes of the middle fibrous layer of the tympanic membrane were observed in the group without cartilage interposition compared to the group with cartilage inserted. This means that autologous cartilage indeed provides a good interface material between two systems with different elastic modules. On the basis of our observations we strongly recommend the interposition of an autologous cartilage disc between a hydroxylapatite middle ear prostheses and the eardrum. Further clinical evaluation of these experimental results is needed, initially by means of an animal experimental study in which the Eustachain tube will be obstructed. Additional evaluation is needed in the human middle ear, including a study concerning the sound conduction mechanism in tympanoplasty after cartilage interposition between the prosthesis and the tympanic membrane.

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Chapter 4

The Groningen Cartilage Cutting Device, a new instrument for tympanoplasty

AGW Meijer, BO Westerlaken, FWJ Albers.
The Groningen Cartilage Cutting Device, a new instrument for tympanoplasty.
The Laryngoscope 1999;109: 2025-7.

Introduction

For many years, otologic surgeons have successfully used biocompatible synthetic materials in tympanoplasty to reconstruct the middle ear air conduction system. The use of synthetic materials instead of autografts and allografts provides significant advantages: they are easy to shape and trim intraoperatively, there is no reimplantation of existing disease (autografts), and there is no transmission of prion-disease (allografts) (1,2,3,4,5).
However, for all these synthetic implants, the intrinsic problems are rejection and extrusion (6,7). With the introduction of highly biocompatible materials, rejection is seldom observed anymore. Extrusion rates can be lowered by interposing a small cartilage disc between a synthetic implant and the tympanic membrane. The literature refers to rates of extrusion varying from 15 - 22%; interposing a cartilage disc reduces extrusion rates to 3 - 6%, which are comparable to those of transplants (8,9,10,11,12,13). Cartilage interposition can interfere with the mechanical properties of the sound-conducting mechanism of the middle ear if the cartilage disc is too thick. If the cartilage disc is too thin, however, extrusion may not be prevented. We describe a standard method of producing a cartilage disc that is thin enough not to interfere with the mechanical properties of the sound-conducting mechanism, yet thick enough to prevent extrusion of the synthetic prosthesis.

Materials and Methods

A new instrument has been designed, developed and used by the otologic surgeons of the Department of Otorhinolaryngology of the University Hospital Groningen to standardize the dissection of a cartilage disc used for interposition between a synthetic middle ear prosthesis and tympanic membrane. The so-called Groningen Cartilage Cutting Device consists of a cutter, a cutting block and a press (Figure 1). The cutter has an internal diameter of 4.1 mm; the cartilage disc thus obtained covers the head of the synthetic prosthesis (4.0 mm) completely. The cartilage cutter can be sharpened and used repeatedly in optimal conditions. The cutting block is made out of metal. It has two depressions on its top: one is 0.4 mm deep and the other 0.5 mm deep. These seem to be the ideal thicknesses required for cartilage interposition because 0.4 is the minimal demanded thickness to avoid damage and undesired transformation of the cartilage disc. A 0.5 mm thick cartilage disc does not interfere with the mechanical properties of the sound conducting mechanism of the middle ear (9). The press is made of Delrin and is used to fixate the cartilage disc on the cutting block.

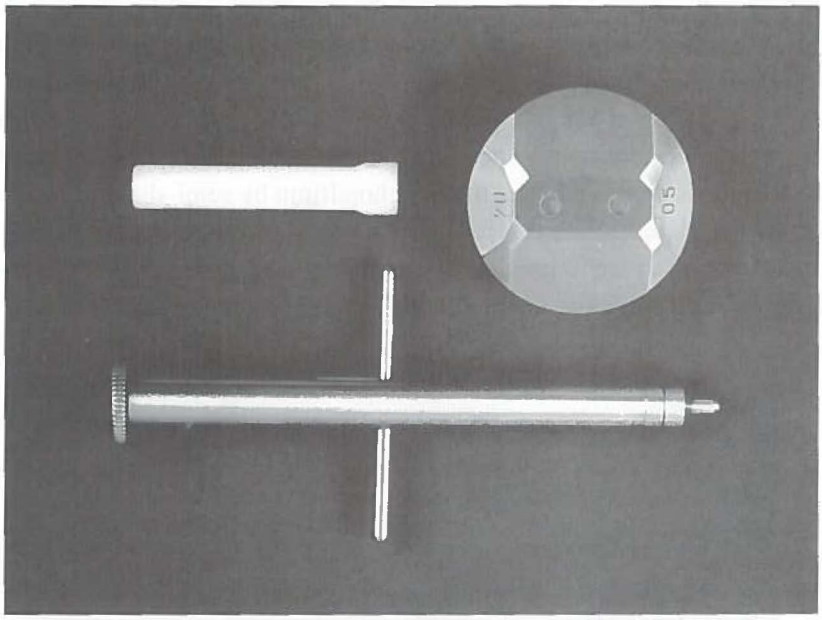

Figure 1. The Groningen Cartilage Cutting Device.

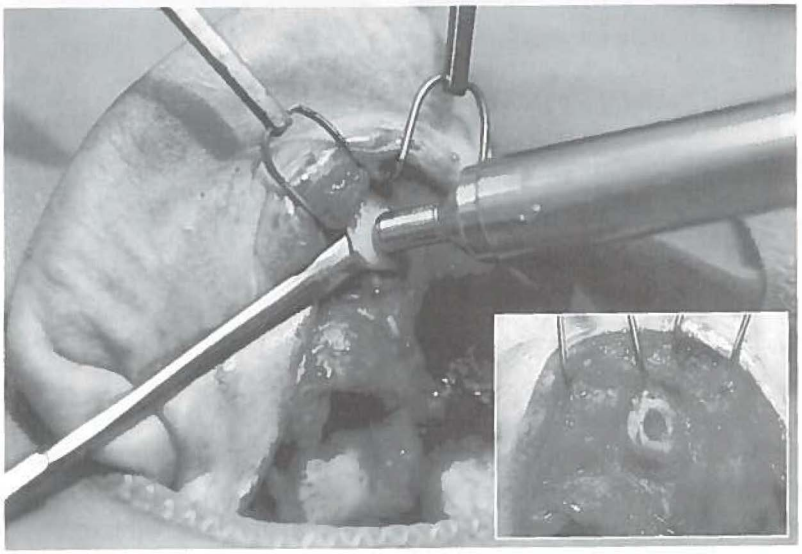

Figure 2. The ear is entered through a postauricular incision and the subcutaneous tissue is separated from the perichondrium using semi-sharp dissection. Using the freer as an anvil the cartilage cutter is used to punch out a small cartilage disc.

Surgical Technique

If the prosthesis is placed directly against the (reconstructed) tympanic membrane, the latter should be reinforced with a flat cartilage disc in the area of contact with the prosthesis (14).

The cartilage disc used for interposition is obtained from the auricle. The ear is entered through a postauricular incision, the auricle is pulled forward, and the subcutaneous tissue is separated from the perichondrium by semi-sharp dissection. Both sides of the perichondrium are separated from the surrounding tissue using a freer. Using this freer as an anvil, the cartilage cutter is used to punch out a small disc of cartilage with both sides still covered with perichondrium (Figure 2).

Figure 3. With the press in one hand, the cartilage disc is fixated in the depression of choice and with the other hand, using a size 11 blade, the cartilage disc is sliced into two parts.

The cartilage disc is put into either one of the two depressions of the cutting block, depending on the thickness necessary for the interposition (0.5 or 0.4 mm). With the press in one hand, the cartilage disc is fixated in the depression of choice, while with the other hand, using a size 11 blade, the cartilage disc is sliced into two parts (Figure 3). The blade is held in a near- horizontal position using the cutting block as a support. This procedure should be done gently with a minimum of force; the blade should do the cutting. The result is a cartilage disc that is either 0.4 or 0.5 mm thick and has a standard diameter. The cartilage disc is subsequently placed on top of the

prostheses with the perichondral side facing the tympanic membrane and the cartilage side facing the prosthesis (Figure 4).

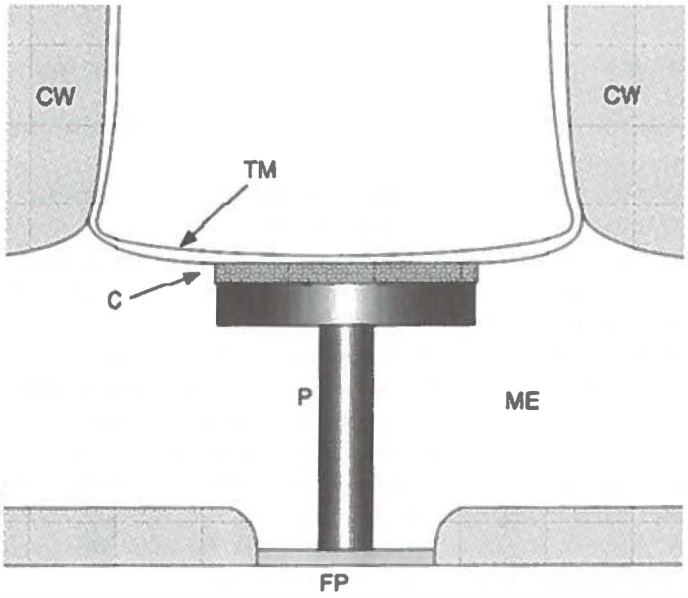

Figure 4. The cartilage disc is placed between the prosthesis and the tympanic membrane. CW = canal wall, TM = tympanic membrane, C = cartilage disc, P = prosthesis, ME = middle ear, FP = foot plate.

Results and Conclusion

The Groningen Cartilage Cutting Device has been successfully used for the last two years by different otologic surgeons in our clinic to dissect cartilage discs needed for interposition during tympanoplasty. Since its introduction, the device has been used, with consistent results, in operations on approximately one hundred patients. In each case, the cartilage disc was easy to dissect, had a standard thickness which did not interfere with the mechanical aspects of sound conduction and was thick enough to prevent extrusion of the prosthesis. In this relatively short follow-up period, we had only one case of extrusion.

The Groningen Cartilage Cutting Device may significantly contribute to tympanoplasty by providing a method for producing standardized discs used for interposition, reducing operating time otherwise needed for trimming and shaping the interposition transplant, and having proven to be an instrument that is simple and easy to use intraoperatively.

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Chapter 5

Histopathology of biocompatible hydroxylapatite-polyethylene composite in ossiculoplasty

AGW Meijer, HM Segenhout, FWJ Albers, HJL van de Want. Histopathology of biocompatible hydroxylapatite-polyethylene composite in ossiculoplasty. ORL 2002;64:173-179.

INTRODUCTION

In recent years, various new synthetic materials have been specially designed for implantation in the middle ear. One of the most frequently used materials at the moment is hydroxylapatite. The biocompatible properties make hydroxylapatite particularly attractive for ossicular chain reconstruction, and also applications in other specialisms; for example, orthopedics (1-12). Hydroxylapatite is a rigid dense calcium phosphate ceramic that conducts vibratory energy reasonably efficiently. The implants in the middle ear become rapidly covered by an epithelial and fibrous layer without signs of a foreign body reaction, suggesting optimal biocompatibility of hydroxylapatite (5-10). However, hydroxylapatite is technically difficult to manipulate intraoperatively, as it is brittle and shatters easily when drilled or trimmed with sharp instruments. As a substitute for the hydroxylapatite shaft, polyethylene was considered as additional material for the design of the middle ear prostheses. Polyethylene is easy to trim and to use intraoperatively. Polyethylene behaves as a biocompatible material, however, when in contact with the tympanic membrane, the material becomes surrounded by macrophages and foreign body giant cells representing rejection (13-18). To combine the properties of biocompatibility and manipulation, a homogeneous material consisting of 40 % hydroxylapatite and 60 % polyethylene was introduced (HAPEX, Entermed). This composition results in a biocompatible material reflecting the mechanical properties of cortical bone, yet is soft enough to cut with a knife. In addition, sound properties benefit from the rigidity of the hydroxylapatite- polyethylene shaft material (19-20). The HAPEX middle ear prostheses consist of a hydroxylapatite head and a hydroxylapatite-polyethylene shaft.

Middle ear epithelium is characterised by the presence of ciliated cells and goblet cells, although the greater part of the middle ear is covered by flat polygonal cells. One of the important functions of the middle ear epithelial cells is their role in the host defence against infection. Tissue reactions to the prosthesis can be subdivided into: reactions at the hydroxylapatite-polyethylene tissue interface; ingrowth of tissue into the pores of the material; aspects related to the covering of the prostheses with fibrous tissue and epithelium; and lastly the accumulation of macrophages and giant body cells associated with a foreign body reaction. Our special interests were focused on the aspects related to the covering of the prostheses and an eventual foreign body reaction to this new prosthesis material.

Studies concerning the aspects related to the covering of hydroxylapatite in the middle ear, showed that hydroxylapatite is rapidly covered by fibrous tissue and epithelial cells, and permits differentiation into the goblet and ciliated cells when in close contact with middle ear mucosa (9,10). No arguments have been found for a foreign body reaction to hydroxylapatite. Until now no studies have been carried

out concerning the covering of the hydroxylapatite-polyethylene composite implants (HAPEX, Entermed) and the possible accumulation of macrophages and giant body cells associated with a foreign body reaction.
The aim of this study was to perform a morphological analysis of the layer covering the hydroxylapatite-polyethylene shaft (HAPEX, Entermed), with special attention to the eventual appearance of foreign body giant cells, macrophages and the possible presence of other cellular inflammatory reactions indicating the cellular phenomena associated with rejection process. The analyses were carried out using light microscopy, transmission electron microscopy and scanning electron microscopy.

Materials and methods

In this study all prostheses consisted of a hydroxylapatite head and a hydroxylapatite- polyethylene composite shaft (HAPEX, Entermed). HAPEX is a homogenous composite of particulate hydroxylapatite reinforced high-density polyethylene mixed in a 40-60 ratio by volume. HAPEX is bioactive and biocompatible (20). The prostheses had been implanted in the human middle ear and were removed during revision surgery after a time interval of 2-30 months (table 1). All implants were positioned between the tympanic membrane and the stapes or stapes footplate. The reasons for revision surgery were residual cholesteatoma or persistent chronic mastoiditis (table 1). We studied the covering layer of 11 retrieved prostheses using light microscopy, transmission electron microscopy and scanning electron microscopy.

case number	interval (months)	diagnosis	
		cholesteatoma	chronic mastoiditis
1	20	+	+
2	17	+	+
3	13	+	+
4	19	+	+
5	14	+	-
6	2	-	+
7	30	-	+
8	unknown	unknown	unknown
9	7	+	+
10	9	+	-
11	15	-	-

Table 1. Surgery-related characteristics of the investigated hydroxylapatite-polyethylene composite implants (HAPEX, Entermed).

Histological processing

After surgical removal, 9 of the 11 prostheses, covered with a membranous-like layer, were immersion fixed in 2.5 % glutaraldehyde in 0.1 M sodium cacodylate buffer, pH 7.4. The specimens were then decalcified for five days in 10 % EDTA, pH 7.4; postfixed in 1% OsO_4 with 1% $K_4Ru(CN)_6$ for two to three hours, and carefully rinsed in distilled water. They were then dehydrated in a graded ethanol series followed by propylene oxide, and infiltrated using a mixture of 1:1 propylene oxide and Spurr`s low viscosity resin for one hour and, finally, using pure resin, overnight. After identification of the membranous-like layer, polymerisation took place after exsiccation in a vacuum. The specimen blocks were trimmed and cut in semithin sections (2µm), and stained with toluidine blue for evaluation by light microscopy (LM). All 9 pieces were further examined by transmission electron microscopy. Ultrathin sections of 100 nm were contrasted with 1% uranyl acetate in 100% methanol and lead citrate. Evaluation was performed using a transmission electron microscope (Philips 201) operating at 40 kV.

Two prostheses were prepared for scanning electron microscopy evaluation. The prostheses were dehydrated, critical point dried according to routine procedures and studied with a field emission scanning electron microscope (Jeol 6301).

case number	fibrous issue	epithelium	macrophages and foreign body cells
1	+	-	-
2	+	+	-
3	+	-	-
4	+	-	-
5	+	+	-
6	+	+	-
7	+	-	-
8	+	-	-
9	-	+	-

Table 2. Microscopical characteristics of the investigated hydroxylapatite-polyethylene composite implants (HAPEX, Entermed).

Results

Observations made using light microscopy and transmission electron microscopy per section are briefly summarized in Table 2. The implants listed in this table were screened, and the results divided into three categories recording the presence of fibrous tissue, epithelial cells and macrophages and foreign body giant cells respectively.

Macroscopy

All but one of the prostheses appeared to be covered with a thin superficial membranous-like layer with small blood vessels. The shafts of the retrieved prostheses made contact with the middle ear mucosa only at the connection point of the stapes or stapes footplate.

Light microscopy

The light microscopy sections showed that half of the prostheses were covered by a thin epithelial outer layer and fibrous tissue and matrix with some capillaries in the deeper parts of this layer. Some prostheses were covered by only a fibrous layer and matrix, without epithelial lining (Figure 1 and 3).

Figure 1. Light microscopical appearance of the matrix that covered the shaft of a HAPEX-middle ear prosthesis after implantation. The outer matrix layer consists of fibroblasts and collagen bundles. The inner matrix layer (asterisk) contains less cells than the outer layer. Inset: the saving in the middle indicates the shaft of the implant (S). The diameter of the saving in the middle differs from the diameter of the prosthesis. This is due to shrinkage and distortion of the tissue due to the procedures of tissue processing. Bar =10 μm. Bar inset = 100 μm.

The epithelial cell layer consisted of flat polygonal cells or cuboidal cells. The epithelial layer varied in thickness between 1, and 3 or 4 cell layers. The fibrous layer consisted predominantly of collagen, fibroblasts, matrix and some capillaries. No macrophages or foreign body giant cells were seen in the epithelial layer, nor in the fibrous layer. None of the prostheses was covered by a cholesteatoma matrix.

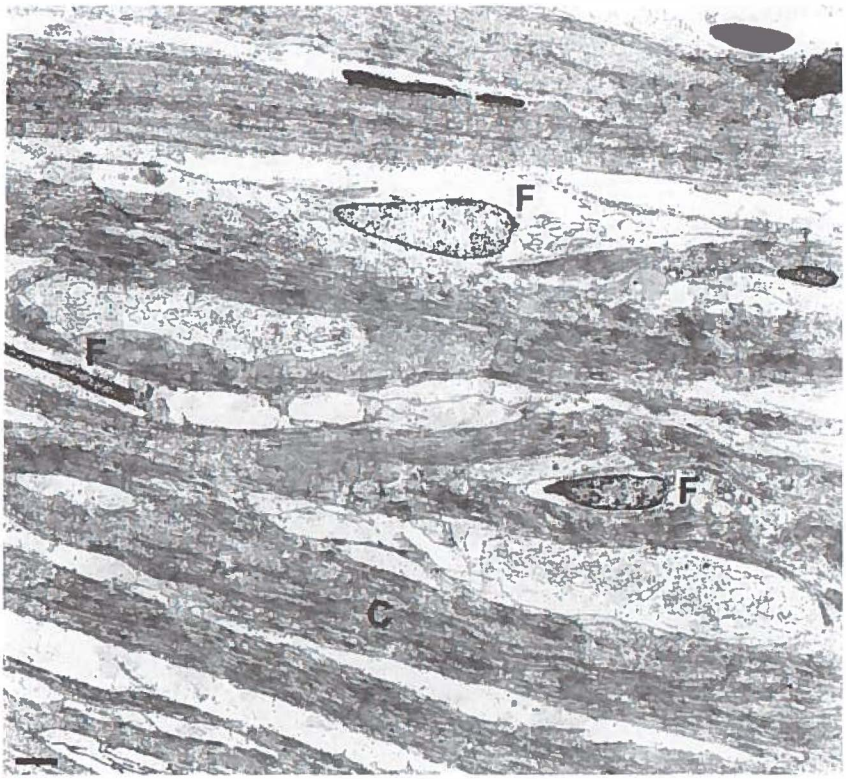

Figure 2. Closer view of figure 1 with transmission electron microscopy. The matrix shows a homogenous layer of random orientated bundles of collagen (C), in between these layers fibroblasts (F) and small capillaries are present. No macrophages or foreign body giant cells could be found. Bar =2 μm.

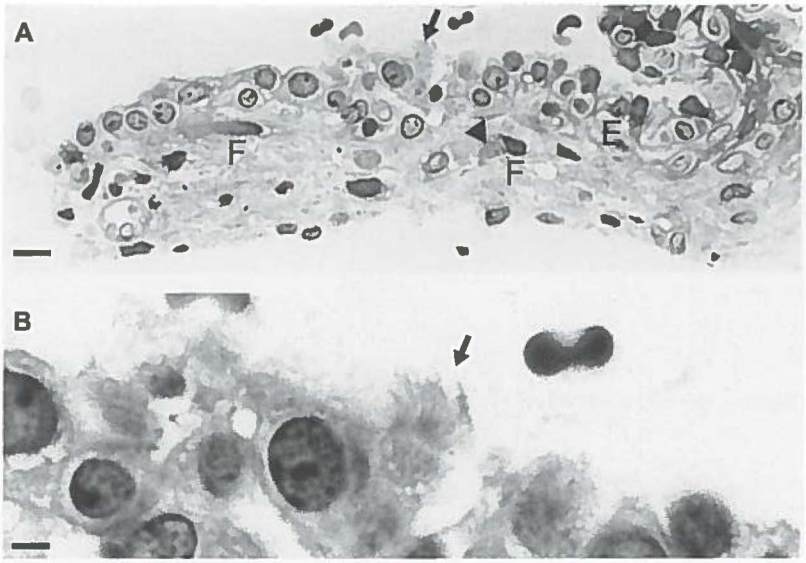

Figure 3. The light microscopical figure shows several layers cuboidal epithelium (E), and below the epithelial layer a cellular matrix of connective tissue and fibroblasts (F) is present, basal mina arrow-head) and ciliated epithelial cell (arrow) are indicated. Bar A =10 μm. Bar B = 4 μm.

Figure 4. Closer view of figure 3 with transmission electron microscopy. The cuboidal epithelial layer shows a normal intracellular morphology. Some cuboidal epithelial cells exhibit dark and pyknotic nuclei with condensed karyoplasm (arrowhead). The cytoplasm contains dilated endoplasmic reticulum (asterisks), whereas other cells have a characteristic morphology of normal epithelial cells (arrow). The cuboidal cells are covered with microvilli (M) and a glycocalyx layer. The electron density of the glycocalyx is caused by ruthenium red staining. Bar =1 μm.

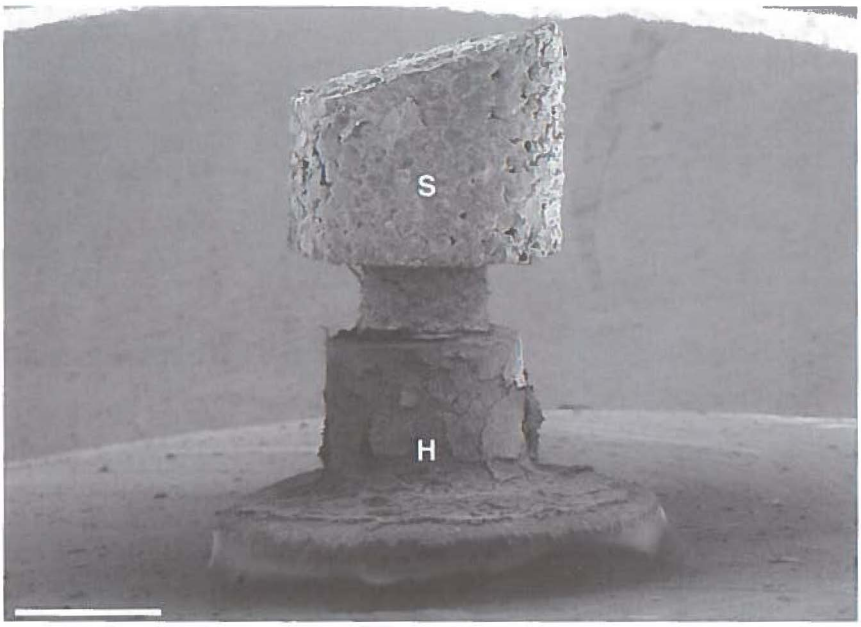

Figure 5. Scanning electron microscopical appearance of a HAPEX middle ear prosthesis consisting of a hydroxylapatite head (H) and a hydroxylapatite-polyethylene shaft (S). The shaft has been trimmed intra-operatively to fit to the appropriate size in the middle ear. The shaft is composed of sintered hydroxylapatite and polyethylene which gives a smooth but irregular surface. Bar = 1 mm.

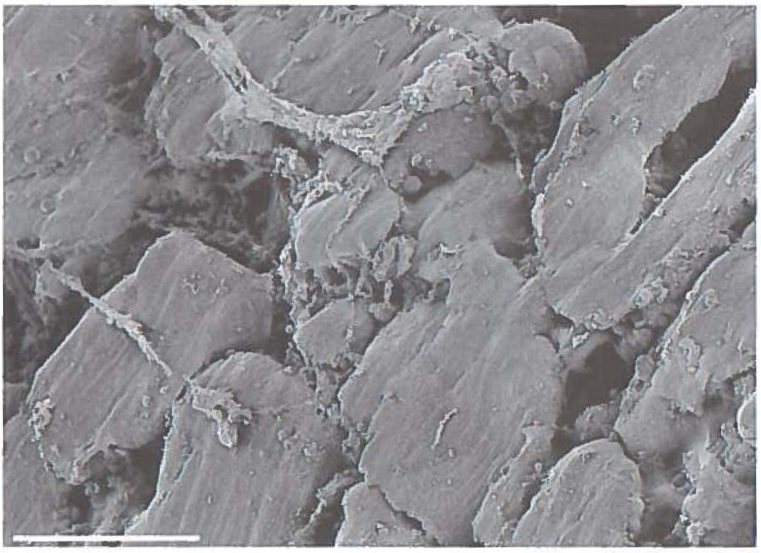

Figure 6. This scanning electron microscopical image allows a closer inspection of the sintered hydroxylapatite-polyethylene shaft. The shaft surface is smooth but irregular with some fibrous adhesions in the surface irregularities. The globular elements are erythrocytes and white blood cells.
Bar = 100 μm.

Transmission electron microscopy

Closer inspection of the epithelial layer with transmission electron microscopy showed various layers of flat polygonal cells and cuboidal cells with microvilli at the apical side (Figure 4). The epithelial cells showed a normal intracellular morphology. Some cuboidal epithelial cells exhibit dark and pyknotic nuclei with condensed karyoplasm, the cytoplasm contains dilated endoplasmic reticulum, whereas other cells have a characteristic morphology for normal epithelial cells. The cuboidal cells were covered with microvilli and a glycocalyx layer. Ciliated epithelial cells were sparse.

Closer study of the fibrous layer by transmission electron microscopy showed fibroblasts in a fine filamentous matrix and randomly oriented collagen fibre bundles and some capillaries (Figure 2). Even after careful inspection of transmission electron microscopic images no macrophages and foreign body giant cells could be found.

Scanning electron microscopy

The single prosthesis that was not covered macroscopically with a membranous-like layer was studied by scanning electron microscopy to inspect the outer layer of the prosthesis for fine structural changes or adhesions of extra cellular material. This scanning electron microscopical evaluation showed a prosthesis-shaft with some fibrous adhesions without a cell layer and matrix (Figure 5 and 6). There was no evidence found for ingrowth of epithelial cells or macrophages and foreign body giant cells. The shaft of the second prosthesis was completely covered by a layer containing fields of flat cells, most likely epithelium, surrounded by a fibrous matrix. There were no foreign body giant cells and macrophages.

Discussion

The purpose of this study was to provide experimental results concerning the covering of the hydroxylapatite-polyethylene composite implants (HAPEX, Entermed) by middle ear epithelium and to determine a possible foreign body reaction to these newly designed prostheses.

The results of our study showed that the surface of the prostheses in half of the cases became covered by a thin outer epithelial layer and an irregular fibrous matrix containing fibroblasts, collagen bundles and capillaries in the deeper parts of this layer. Some areas showed only a fibrous layer, without epithelial cells. The epithelial cell layer consisted of flat polygonal cells and some cuboidal cells with microvilli at the apical side. In one case, cilia on the epithelial surface were observed. Most cells showed a normal ultrastructural morphology. Our findings are in agreement with studies on the epithelial covering of clinically retrieved hydroxylapatite prostheses by van Blitterswijk et al (9,10).

Special attention was paid to the appearance of macrophages and foreign body giant cells. In the epithelial layer and the fibrous layer no foreign body giant cells or macrophages were found. This finding is in contrast to the many reports in the past on the light microscopic appearances of Proplast and Plastipore prostheses after varying periods in the middle ear. Most of these have referred to the presence of foreign body giant cells and macrophages representing rejection of the prosthesis (13-17). In these studies, however, the prostheses were completely made of polyethylene, including the head of the prostheses.

In conclusion: in clinical practice hydroxylapatite-polyethylene composite implants (HAPEX, Entermed) are completely covered by fibrous tissue, mostly in combination with an outer epithelial layer, without any foreign body reaction to the implant material. The high biocompatibility and functional qualities of the material establish the prosthesis as being very suitable for reconstructive middle ear surgery.

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Chapter 6

Validation of hearing results in tympanoplasty, a preliminary report

AGW Meijer, FWJ Albers, AVM de Visscher, EM TenVergert.
Validation of hearing results in tympanoplasty, a preliminary report.
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Introduction

More and more attention is been focussed on the effectiveness of treatment modalities in relation to the costs. Evaluation of treatment results in reconstructive middle ear surgery with special regard to quality of live aspects is, therefore, of increasingly importance.
The results of reconstructive middle ear surgery are frequently reported by the postoperative closure of the air-bone gap or the improvement in air-conduction thresholds (1). These parameters may reflect the technical success of middle ear reconstruction, but do not evaluate the effect of surgery on binaural hearing ability reflecting subjective hearing (2,3,4,5).
In the literature two methods have been proposed for predicting the patient hearing benefit in reconstructive middle ear surgery: the Rule of Thumb (6) and the Glasgow Benefit Plot (7). According to the Rule of Thumb patient benefit is achieved when the mean postoperative air-conduction threshold (for 0.5 to 4 kHz) in the operated ear is $\leq$ 30 dB HL or when the postoperative interaural difference is $\leq$ 15 dB HL. In the Glasgow Benefit Plot the pre- and postoperative plots of the air-conduction thresholds in both ears are used to evaluate binaural hearing results. According to this method, three main preoperative impairment groups are identified. The potential patient benefit is represented in four different postoperative categories: category a: bilateral normal hearing, category b: unilateral normal hearing, category c: the operated ear improves, but is still impaired, category d: symmetric, but impaired thresholds. The postoperative categories a and b are considered to represent the most significant patient benefit, while the category c and d are regarded as less beneficial.
Both methods evaluate the postoperative binaural hearing ability and, therefore, seem to provide a realistic prognosis to predict the patient benefit after middle ear surgery. However, in both methods 30 dB HL as maximum air-conduction threshold is used as arbitrary limit to define normal or social acceptable hearing. Validation of the definition of normal of social acceptable hearing is obligatory for reliable preoperative selection of patients for reconstructive middle ear surgery. In the present study, this validation was performed by means of a questionnaire measuring the subjective hearing ability. Correlations were observed between the three possible answer categories concerning the question hearing ability in general and the mean air-conduction thresholds.

Patients and methods

In a prospective study 34 patients (male: 27, female: 7; mean age: 37 years; range: 8-59 years) were included who underwent a closed or open technique mastoidectomy in combination with a tympanoplasty. Almost all patients were previously operated

and suffered from chronic otitis media and mastoiditis or cholesteatoma. All patients received an ossicular reconstruction with a hydroxylapatite prosthesis (Smith & Nephew Richards Inc.) according to the ossicular defect (Table I).

Tympanoplasty: stapes present
1. Wehrs incus prosthesis (n=3)
2. PORP (partial ossicular replacement prosthesis) (n=16)
3. Applebaum incudostapedial joint prosthesis (n=1)
Tympanoplasty: stapes absent
1. Wehrs incus-stapes prosthesis (n=3)
2. TORP (total ossicular replacement prosthesis) (n=11)

Table I. Ossicular reconstruction with hydroxylapatite prostheses according to the ossicular defect (n=34).

A cartilage plate between the head of the prosthesis and the undersurface of the tympanic membrane was interposed to prevent extrusion of the prosthesis. Preoperatively and three months postoperatively the following audiometric tests were performed: pure-tone audiometry including the air- and bone-conduction threshold, speech audiometry and tympanometry. The subjective hearing ability was established preoperatively, and three months postoperatively by a questionnaire. The questionnaire consisted of ten questions containing the following dimensions: speech intelligibility in quiet (1 question), speech intelligibility in noise (1 question), hearing impairment at home (2 questions) and in social surroundings (4 questions). One question was focussed on the subjective hearing ability in general and another question was directed to the hearing improvement postoperatively. The internal consistency was determined with cronbach α coefficient. An α coefficient of 0.70 or higher was considered as sufficient (Nunally's criteria, 1978). The answers of the questionnaire were classified in a three and four point scale with a wide variety of response possibilities.
The statistical analysis of the results included oneway anova and student's t-test. Statistical significance was regarded at p values $\leq$ 0.05.

Results

The results of middle ear reconstruction in 34 patients are described by the pre-operative and three-months postoperative air-conduction and bone-conduction thresholds (0.5-4 kHz), speech audiometry thresholds and the pre- and postoperative air-

bone gap (Table II). The mean air-conduction threshold decreased significantly from 47 dB HL preoperatively to 36 dB HL postoperatively, while the bone-conduction threshold remained unchanged. The mean speech audiometry threshold decreased significantly from 34 dB HL to 22 dB HL. The postoperative air-bone gap showed a significant improvement from 27 dB HL to 16 dB HL. No significant differences in the postoperative air-conduction thresholds were found between patients with incus interposition and patients with incus-stapes interposition ($p \leq 0.05$).

	Preoperative	Postoperative
Air-conduction	47 (±13)	36 (±11)*
Bone-conduction	20 (± 8)	20 (±10)
Speech audiometry	34 (±11)	22 (±11)*
Air-bone gap	27 (±11)	16 (± 6) *

* : statistically significant (paired T-test, $p \leq 0.05$)

Table 2. Mean hearing results after middle ear reconstruction in dB HL (n=34).

With respect to reliability, the average cronbach α, estimate was 0.89 (range 0.88-0.89) for the questions 1, 4, 5 and 10. Question 2, 3 and 6 gave only a rise of cronbach $\alpha = 0.90$. Question 7, 8 and 9 were excluded because of little connection with the measured values. Applying Nunally's criteria (1978) for a reliable test (cronbach $\alpha \geq 0.70$) it may be concluded that question 1, 4, 5 and 10 may be considered most reliable.

The results of the questionnaire with regard to the question preoperative and postoperative hearing ability in general (good, moderate, bad) and the question hearing improvement of the operated ear (improved hearing, unchanged hearing, reduced hearing) are summarized in Table III and IV. Adequate response on the pre- and postoperative questionnaire was not established in all cases. Incomplete questionnaires were excluded from analysis. Concerning the question hearing improvement of the operated ear three months postoperatively, 63% of the patients regarded the hearing ability of the operated ear improved. In Table V the correlation between the question subjective hearing ability in general and air-conduction threshold three months postoperatively is described. Per answer category: good-moderate-bad the mean hearing results in dB HL were calculated. These results show a clear relationship between the subjective hearing quality and the degree of the air conduction threshold.

	Preoperative (n=32)	Postoperative (n=31)
Good ability	3	1
Moderate ability	11	14
Bad ability	18	7

Table 3. The results of the questionnaire with regard to the preoperative and postoperative subjective hearing ability in general of the operated ear.

	Postoperative (n=30)	
improved hearing	19	(63%)
unchanged hearing	8	(27%)
reduced hearing	3	(10%)

Table 4. The results of the questionnaire with regard to the postoperative subjective hearing improvement of the operated ear.

subjective hearing ability	air-conduction threshold	F	P
		11.9	≤.01
good	27 (20-30)		
moderate	36 (20-45)		
bad	49 (45-55)		

Table 5. Relation between the three possible answer categories of the question mean hearing ability in general and the mean air-conduction threshold (dB HL) to match per answer category, three months postoperatively (n=31).

Discussion

In this prospective study the short-term results of middle ear reconstruction with hydroxylapatite prostheses indicate a significant improvement of the hearing ability. Almost all patients suffered from chronic otitis and mastoiditis or cholesteatoma and underwent revision open or closed mastoidectomy in combination with tympanoplasty, which can explain the limited extent of hearing improvement. No significant differences in hearing ability were observed between patients with incus interposition and incus-stapes interposition. These results are in contrast to other studies, which report an association between the loss of the stapes arch and a significantly poorer outcome of postoperative hearing results (3,4).

The arbitrary limit of normal or social acceptable hearing is defined as the maximum air-conduction threshold of 30 dB HL (6,7). Validation of the definition of normal of social acceptable hearing is essential for the preoperative selection and postoperative evaluation of patients in reconstructive middle ear surgery. In this study we found a correlation between the subjective hearing ability and the air-conduction threshold three months postoperatively that supports the definition of 30 dB HL as maximum limit for normal hearing. However, further statistical validation in a more extensive prospective study is necessary for the accurate application of the Rule of Thumb or the Glasgow Benefit Plot in the preoperative selection and postoperative evaluation of patients in reconstructive middle ear surgery.

Conclusions: the results of the study support 30 dB HL as maximum air-conduction threshold to define normal or social acceptable hearing. The significance of the cut off level of normal or social acceptable hearing in dB HL should be further validated in a larger prospective study.

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Chapter 7

Reliability and validity of the (modified) Amsterdam Inventory for Auditory Disability and Handicap

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INTRODUCTION

Hearing impairment is generally quantified solely using information from subjective audiometry, including pure-tone and speech audiometry. This quantification is performed for diagnostic and rehabilitative purposes, the follow-up of intervention procedures and medicolegal assessments. However, to describe the overall effect of a hearing impairment the specification of hearing status in terms of pure-tone thresholds alone has some limitations. For patients with a hearing impairment, the ability to communicate depends both on sensory and non-sensory factors. General communication skills, emotional aspects, the behavior of friends, family and co-workers, all can have impact on communication. It is not surprising that the performance of patients in typical communication situations is not predictable from audiometric measures alone. Audiometric tests do not assess the non-sensory variables that contribute to actual communication, according to several authors (1-12). Audiometric measures can be supplemented by a questionnaire or a self-report inventory. The advantages of self-report are convenience and external validity (at least within the context of the questions asked). Performance measures are strictly limited to the actual task used in the performance test and do not necessarily measure the effect of loss of hearing and functional behaviour. On the other hand, performance testing has the advantage of being able to provide reproducible results and is less prone to bias from extraneous factors such as exaggeration, personal opinion and inappropriate self-perception.

Because hearing disability[1] represents the difficulties experienced in everyday hearing, we searched for a specific self-assessment questionnaire to quantify it. During the last decade, many hearing questionnaires have been developed. Most self-assessment questionnaires are designed for a specific domain area (measurement objective) and the majority of the questions relate to communication. Some focus on hearing handicap, some on disability, some on social surroundings or emotional factors and some are specially designed for only older people (1-3,5,7,10,13,14)The instrument that fulfilled our requirements was the Amsterdam Inventory for Auditory Disability and Handicap (AIAD) developed by Kramer et al. (11), because it is a Dutch instrument, tested on a Dutch patient population with all types of hearing losses (conductive, perceptive and mixed) that concentrates on all aspects of hearing disability. In daily listening, the basic dimensions of hearing disability (besides communication) are important. These disability dimensions are discrimination and detection of sounds, auditory localization and ability to understand speech in noisy and in quiet surroundings. The AIAD was developed because there were no appropriate standardized instruments available for assessing all the above-mentioned aspects of hearing disability. It contains 30 items describing hearing disability and its consequences.

In the present study special emphasis was placed on the statistical aspects of scores, because these properties place limits on the clinical suitability of the questionnaire. Some aspects of the AIAD had already been statistically analyzed by Kramer et al. (11,12). However, the reliability and validity had not been extensively investigated. Moreover, in the original analysis of the AIAD, patients wearing a hearing aid were included, which introduced an undesirable bias.

In the present study we used a modification of the AIAD, denoted as (m)AIAD. This consisted of the first part of 28 rather than 30 questions from the original inventory. The original questionnaire consists of three parts per question: an A-, B- and C-part. The A-part of each question assesses the degree of disability. The B-part deals with former hearing performance. In the C-part, the respondent is asked to judge how handicapped he or she feels. Our interest was hearing disability, so we omitted the B- and C-part, with permission from the first author of the AIAD. Furthermore, the authors of the AIAD performed their statistical analyses only on the A-part of the questionnaire. Important psychometric properties in testing a questionnaire are reliability and validity. The aim of this study was to analyze the (m)AIAD psychometrically by means of the assessment of its reliability and validity. Reliability was tested by measuring internal consistency, split-half correlation, test-retest reproducibility, while factor analysis was also performed. Validity was tested by measuring construct and criterion validity. For the psychometric analyses of construct validity, a second disability questionnaire was used: the translated version of the Hearing Disability Questionnaire, described by Lutman et al. (5). This questionnaire has been statistically validated and proven appropriate and has, therefore, been extensively used to measure auditory handicap and disability (1-3,4,5,10).

Patients and methods

Subjects

A total of 125 patients who visited the Department of Otorhinolaryngology of the University Hospital Groningen and who met the criteria for inclusion were included in the study. The requirements for participation were age between 15 and 65, no known learning disability and not wearing a hearing aid. Subjects under 15 years of age were regarded as too young to deal with the questions. The upper age limit was set at 65 years, in accordance with the instructions for the use of the AIAD, as increasing age involves specific hearing problems, a decrease in reporting disability and altered social surroundings. All types (conductive, perceptive and mixed) and severities of hearing loss (varying from no hearing loss to severe hearing loss) were included. All patients were asked to participate in the study, which included giving their informed consent. Air- and bone-conduction thresholds were measured on the day of the patient`s visit to the ENT department.

To correlate the scores on the (m)AIAD with the scores on an already validated questionnaire, the HDQ (5) was used. The latter was translated into Dutch. The (m)AIAD (appendix 1) and the translated version of the HDQ (original version in appendix 2), together with a letter of introduction and a stamped and addressed reply envelope were issued to the patients to take home. They were asked to fill them in completely and to return them as soon as possible. The time of visiting the ENT department was defined as t_1. Exactly one month later (t_2), the same questionnaires with a covering letter and a stamped and addressed reply envelope were mailed to the patient`s home address for test-retest examination. The inventories were distributed to 125 subjects and were returned by 108 subjects. Of these 108 subjects, 14 were excluded because of missing and incomplete answers. The age of the subjects ranged from 17 to 65, mean 41 years, median 45 years. There were 53 females and 41 males included in the study. At t_1 pure-tone audiometry was performed on all subjects. Based on the assumption that hearing did not change within one month, the mean hearing threshold measured at t_1 was also used at t_2. The total scores on both questionnaires were calculated at t_1 and t_2. Hearing losses were classified as perceptive, mixed or conductive. In the population of 94 subjects, 24 were normally or near normally hearing (both ears showing hearing levels 20 dB), 27 subjects had perceptive hearing losses, 29 subjects had mixed hearing losses and 14 subjects had conductive hearing losses.

Audiometry

Pure-tone audiometry was performed on all subjects at t_1. Air- and bone-conduction thresholds were obtained at 0.5, 1, 2 and 4 kHz. The mean air- and bone-conduction thresholds were calculated across the four frequencies for each ear and then averaged over the two ears, because in most situations hearing is a binaural function with an essential contribution of the contra-lateral ear. For further statistical analyses the mean hearing threshold (averaged over the two ears) was calculated in two ways, worse ear : better ear weighted in the ratio 1:4 and also with equal weighting (1:1). The weighing of 1:4 in favor of the better ear has widespread use in the assessment of disability in the United Kingdom according to Lutman et al. (5). The latter value (1:1) was chosen to be used as the hearing threshold for a specific patient at both times of measurement. In the case of a totally deaf ear, the average threshold for that ear was taken as 120 dB HL.

Self-reported disability

Responses to each question were coded on a scale of 0-3 for the (m)AIAD and a 0-2 or 0-3 scale for the HDQ, depending on the number of alternatives per question. The higher the score, the smaller the perceived hearing difficulties were. The total score on a list was calculated for each subject by adding the scores for each question. Questions 18 and 30 of the AIAD were excluded, as the authors of the AIAD (11)

also have excluded these questions after statistical analyses. The maximum score for the (m)AIAD is 84 while the maximum score for the HDQ is 24.

Statistical analyses

The psychometric adequacy of the (m)AIAD was determined by testing reliability and validity. Comparable studies testing the psychometric adequacy of self-report hearing inventories are described by diverse authors (7-9,14-19).

Reliability: reliability was tested by calculating internal consistency (Cronbach alpha), split-half correlation (Guttman), test-retest reproducibility (Pearson R). Also, factor analysis was performed: the individual questions of the (m)AIAD were categorized for the 5 factors, in the same way as they were subdivided by the authors of the AIAD, and Cronbach alpha was calculated for each factor.

Validity: validity was estimated by measuring construct and criterion validity. Construct validity is concerned with the extent to which a particular measure relates to other measures in a manner consistent with theoretical hypotheses concerning the concepts (or constructs) being measured. Construct validity was estimated by correlating scores on the

(m)AIAD with those for the HDQ (Pearson R). Criterion validity can be estimated by correlating scores on the predictor test with scores on the criterion variable (defined as the gold standard for that purpose). We chose hearing thresholds in dB HL as the gold standard for determination of hearing. Criterion validity was estimated by correlating the scores for the (m)AIAD with the audiometric measurements (Spearman R). Psychometric analysis was performed on the full set of data.

All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS, version 8.0) and $p < 0.05$ was considered as a significant result.

Results

Audiometry and questionnaire

The mean pure-tone average for the 94 subjects was 32 dB HL (table 1). The mean total score on the (m)AIAD for these subjects was 64 points, at t_1 and at t_2.

For all 28 questions, four different answers were possible. The frequency distribution in our study population showed that for most questions all the 4 possible answer categories were used almost equally often. This means that almost all answers to the questions showed great variability, except for questions 2, 8 and 23. Therefore, almost all items measure individual differences.

Correlations were computed between scores for all the different questions. Both at t_1 and t_2, scores for almost all questions showed substantial positive correlations with the other questions, except for questions 2 and 8, for which scores showed small correlations ($R \leq 0.3$) with whose for the majority of the other questions.

	Hearing level better ear (dB HL)	Hearing level worse ear (dB HL)	Hearing level both ears (dB HL)	Total score (m)AIAD on t_1	Total score n(AIAD) on t_2
Mean	21	42	32	64	64
Median	18	35	30	66	68
Maximum	10	10	70	84	84
Minimum	65	120	10	26	23

Table 1. The mean, median, maximum and minimum hearing thresholds in dB HL (averaged across 0.5, 1, 2, 4 kHz) and the total scores on the (m)AIAD at t_1 and t_2 for all 94 subjects. The mean hearing thresholds are shown for the worse ear, the better ear, and also averaged over both ears (1:1).

Reliability

Reliability analysis for the answers to all 28 questions at t_1 yielded a Cronbach alpha of 0.96 (table 2) for internal consistency and a Guttman split-half correlation of 0.93, with coefficient $\alpha = 0.91$ for part 1 and 0.92 for part 2. Test-retest reproducibility for the total score on the (m)AIAD at t_1 and t_2 was high (Pearson correlation coefficient =0.90, $p<0.001$) (figure 1).

Internal consistency	Cronbach alpha=0.96
Split-half correlation	Guttman split-half=0.93 Coefficient alpha for part 1 = 0.91 Coefficient alpha for part 2 = 0.92
Test-retest reproducibility	Pearson correlation coefficient=0.90, $p<0.001$

Table 2. Measures of reliability: internal consistency, split-half correlation and test-retest reproducibility.

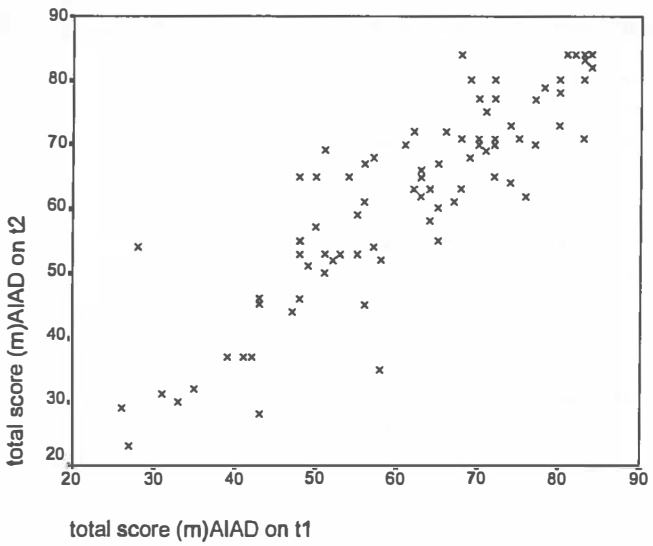

Figure 1. Test-retest reproducibility. Total score on the (m)AIAD at t_2 versus total score at t_1. Some data points overlap.

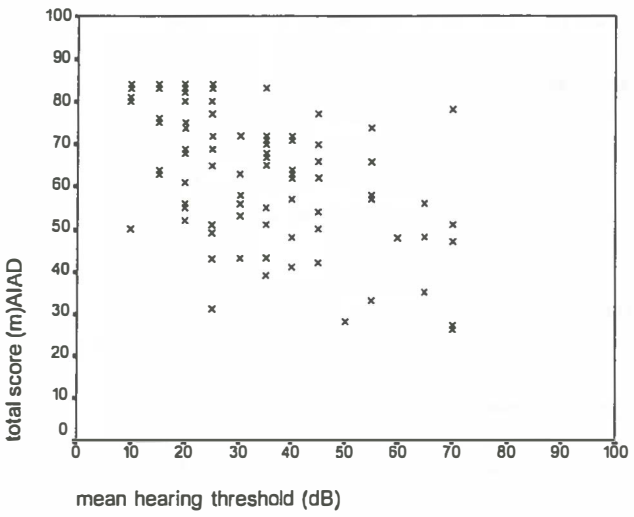

Figure 2. The total score on the (m)AIAD plotted against the mean hearing threshold in dB HL averaged over both ears. Some data points overlap.

Item	Factor	Cronbach Alpha
	Discrimination of sounds	0.88
5	Do you recognize members of your family by their voices?	
6	Can you recognize melodies in music or songs?	
17	Can you discriminate the sound of a car and a bus?	
24	Can you hear rhythm in music or songs?	
26	Can you distinguish intonations and voice inflection in people's voices?	
29	Can you recognize and distinguish different musical instruments?	
23	Can you distinguish between male and female voices?	
4	Can you hear cars passing by?	
	Auditory localization	0.88
3	Do you immediately hear from what direction a car is approaching when you are outside?	
9	Can you hear from what corner of a lecture room someone is asking a question during a meeting?	
15	Do you immediately look in the right direction when somebody calls you in the street?	
27	Do you hear from what direction a car horn is coming?	
21	Can you hear from what corner of a room someone is talking to you being in a quiet house?	
	Intelligibility in noise	0.91
1	Can you understand a shop assistant in a crowded shop?	
7	Can you carry on a conversation with someone during a crowded meeting?	
13	Can you easily carry on a conversation with somebody in a bus or car?	
19	Can you follow a conversation between a few people during dinner?	
25	Can you carry on a conversation with someone in a busy street?	
	Intelligibility in quiet	0.75
14	Can you understand the presenter of the news on TV?	
20	Can you understand the presenter of the news on the radio?	
8	Can you carry on a telephone conversation in a quiet room?	
11	Do you recognize a presenter on TV by his/her voice?	
12	Can you understand text that's being sung?	
	Detection of sounds	0.79
16	Can you hear noises in the household, like running water, vacuuming, a washing machine?	
22	Can you hear the doorbell at home?	
28	Do you hear birds singing outside?	
10	Can you hear somebody approaching from behind?	
2	Can you carry on a conversation with somebody in a quiet room?	
	Excluded items:	
18	Do you experience that music is too loud for you, while others around don't complain about the loudness?	
30	Do you miss parts of music while listening to music or songs?	

Table 3. Factor structure of the items of the (m)AIAD. The individual questions were categorized for the five factors, according to the subdivisions of the original version of the AIAD by Kramer et al. (1995). Cronbach Alpha was calculated for each factor

The individual questions were categorized into five factors, according to the classification by the authors of the AIAD (table 3). Cronbach alpha was calculated based on mean scores for each factor, and was 0.88 for factor 1, 0.88 for factor 2, 0.91 for factor 3, 0.75 for factor 4 and 0.79 for factor 5.

Validity

Construct validity: the total score on the (m)AIAD was correlated with the hearing threshold averaged over both ears, for the 1:1 and for the 1:4 weighing of the ears. The Spearman correlation coefficient was 0.59 and 0.56 respectively, $p<0.001$ (table 4 and figure 2). The total score on the (m)AIAD was also correlated with the hearing threshold for only the better and the worse ear, showing a Spearman correlation coefficient of 0.41 and 0.52 respectively ($p<0.001$).

Criterion validity: the correlation between the total scores on the (m)AIAD and on the Hearing Disability Questionnaire was 0.81 and 0.83 (Pearson correlation coefficient, $p<0.001$) at t_1 and t_2, respectively (table 4 and figure 3).

Correlation between:	Pearson correlation coefficient ($p<0.001$*)
(m)AIAD and average hearing threshold (1:1)	0,59*
(m)AIAD and average hearing threshold (4:1)	0,56*
(m)AIAD and HDQ at t_1	0,81*
(m)AIAD and HDQ at t_2	0,83*

Table 4. Measures of validity. Construct validity was obtained by correlating the total score on the (m)AIAD with the average hearing threshold for 1:1 and 1:4 weighing of the ears (worse ear : better ear). Criterion validity was obtained by correlating the total score on the (m)AIAD with the total score on the HDQ.

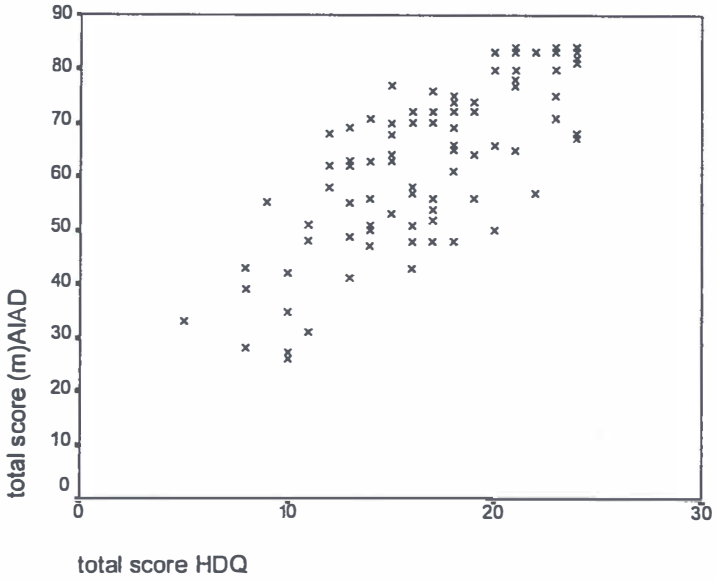

Figure 3. The total score on the (m)AIAD plotted against that for the HDQ at t_1. Some data points overlap.

Discussion

The *reliability* of the (m)AIAD was found to be highly satisfactory, with substantial positive correlations of each question with the majority of the remaining questions (except questions 2 and 8), with good internal consistency (Cronbach alpha), with high split-half correlations and with a high test-retest correlation. The Cronbach alpha`s all exceeded the 0.80 criterion, which is regarded as adequate for clinical purposes according to Nunnally and Bernstein (17). Because the retest occurred one month after the first test, the probability of remembering the original answers is assumed to be minimal. Categorizing the questions in terms of the factors, in the same way as they were classified by the authors of the AIAD, showed rather high Cronbach alpha values for each factor. This is in agreement with the outcome of factor analysis by the authors of the AIAD. The five separate factors, which are the five basic aspects of auditory functioning, were interpreted by Kramer et al. (11) as: discrimination of sounds, auditory localization, intelligibility in noisy surroundings, intelligibility in quiet surroundings and detection of sounds.

The *validity* of the (m)AIAD was also satisfactory. The correlation between the (m)AIAD score and the hearing threshold was moderate but significant. This is in agreement with findings in the literature for other questionnaires (6,7,14) and does not show any inadequacy of self-assessment; it may be interpreted as a limitation in comparing audiometric impairment data with individual responses to self-assessment questionnaires. This also underlines the notion that hearing disability does not depend solely on a person`s audiogram. In addition, the moderate correlation can be partly attributed to measurement error and non-audiological factors such as age, IQ and personality. The value of 0.8 for the correlation between the total score on the (m)AIAD and the already validated HDQ is reassuringly high.

The weighting factors (1:1 or 4:1), used to calculate the mean hearing loss from the contribution of the better and poorer ear, did not show a significant difference for the correlation between hearing loss and questionnaire score. This is in agreement with the findings of Lutman et al. (5), who could not demonstrate any significant differences in the correlation coefficients for any of the questionnaire components by varying the weighing between 2:1 in favor of the worse ear and 7:1 in favor of the better ear.

In conclusion, the psychometric adequacy of the (m)AIAD was tested by measuring reliability and validity. Both were satisfactory. The results of the present analysis indicate that the (m)AIAD is a promising and reliable tool in the assessment of hearing impairment in daily life.

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APPENDIX 1:

The Amsterdam Inventory for Auditory Disability and Handicap

1 Can you understand a shop assistant in a crowded shop?
2 Can you carry on a conversation with someone in a quiet room?
3 Do you immediately hear from what direction a car is approaching when you are outside?
4 Can you hear cars passing by?
5 Do you recognize members of your family by their voices?
6 Can you recognize melodies in music or songs?
7 Can you carry on a conversation with someone during a crowded meeting?
8 Can you carry on a telephone conversation in a quiet room?
9 Can you hear from what corner of a lecture room someone is asking a question during a meeting?
10 Can you hear somebody approaching from behind?
11 Do you recognize a presenter on TV by his/her voice?
12 Can you understand text that's being sung?
13 Can you easily carry on a conversation with somebody in a bus or car?
14 Can you understand the presenter of the news on TV?
15 Do you immediately look in the right direction when somebody calls you in the street?
16 Can you hear noises in the household, like running water, vacuuming, a washing machine?
17 Can you discriminate the sound of a car and a bus?
19 Can you follow a conversation between a few people during dinner?
20 Can you understand the presenter of the news on the radio?
21 Can you hear from what corner of a room someone is talking to you being in a quiet house?
22 Can you hear the door-bell at home?
23 Can you distinguish between male and female voices?
24 Can you hear rhythm in music or songs?
25 Can you carry on a conversation with someone in a busy street?
26 Can you distinguish intonations and voice inflection in people's voices?
27 Do you hear from what direction a car horn is coming?
28 Do you hear birds singing outside?
29 Can you recognize and distinguish different musical instruments?

Excluded items:
18 Do you experience that music is too loud for you, while others around don`t complain about the loudness?
30 Do you miss parts of music while listening to music or songs?

Each question is divided into 3 parts, which all refer to the same situation.
In the A-part the respondent is asked to judge how he/ she experiences auditory difficulties in the mentioned situation. Subjects are asked to respond on the basis of their experiences without a hearing aid.
In the B-part the respondent is asked to judge how he/ she experienced the auditory difficulty in the mentioned situation in the past.
In the C-part the respondent is asked to judge how handicapped he/ she feels by having difficulties in hearing in the mentioned situation.

In the A- and B- part of the inventory the 4 answer categories are as follows: almost never, occasionally, frequently and almost always. In the C-part the 4 answer categories are: no, slightly, moderately and considerably.

APPENDIX 2:

The Hearing Disability Questionnaire

1 Can you follow the television news when the volume is turned up only enough to suit other people? Easily- with some difficulty- with great difficulty- not at all.
2 Can you follow what is being said on the radio news when the volume is turned up only enough to suit other people? Easily- with some difficulty- with great difficulty- not at all.
3 Do you turn your head the wrong way when someone calls to you? Never- rarely- quite often- very often.
4 If you are with a group of people and someone you can't see starts to speak, are you able to tell where the person is sitting? Usually- sometimes- not usually.
5 How difficult do you usually find it to follow somebody's conversation when other people are talking close by? Great difficulty- some difficulty- no difficulty.
6 When talking in a quiet room with someone who is a clear speaker, how much difficulty do you have in understanding what they are saying? No difficulty, some difficulty, great difficulty.
7 How often does any hearing problem you may have restrict your enjoyment of your social and personal life, compared to others around you? Never- rarely- quite often- very often.
8 Do you get the feeling of being cut off from things because of difficulty in hearing? Very often- quite often- rarely- never.
9 Do any hearing difficulties you may have lead to embarrassment? Very often- quite often- rarely- never.

Chapter 8

Relation between change of hearing and (modified) Amsterdam Inventory for Auditory Disability and Handicap score.

AGW Meijer, HP Wit, FWJ Albers.
Relation between change of hearing and (modified) Amsterdam Inventory for Auditory Disability and Handicap score.
Submitted.

INTRODUCTION

In a previous psychometrical study we analysed the (modified) Amsterdam Inventory for Auditory Disability and Handicap (further indicated as (m)AIAD), original version by Kramer et al. (1), in a cohort of normal as well as hearing impaired subjects (2). The reliability as well as the validity of the questionnaire were found to have satisfactory high values, indicating that the (m)AIAD is a promising tool for the assessment of hearing impairment. However, a hearing disability instrument must also be statistically proven valid for measuring changes in hearing ability when hearing thresholds change as a result of intervention.

Our eventual purpose is to use the (m)AIAD in a large patient cohort for measuring the effect of middle ear surgery with the aim to improve hearing. Therefore in the present preliminary study we investigated the relation between change in hearing thresholds (dB HL) as a result of middle ear surgery (not primary to improve hearing, but to cure the disease) and change in subjective hearing ability as expressed by the (m)AIAD score. To determine if the surgical intervention has affected the communication performance, it is necessary to determine whether the observed change in the individual score on the (m)AIAD is larger than would be expected without intervention.

To assess change for individuals, information about test-retest variability in scores is indispensable. In the psychometric analysis of the (m)AIAD (2) the test-retest reliability was already determined; the correlation between test and retest scores was satisfactory high ($r = 0.90$).

In comparable studies the test-retest correlations showed similar values for other inventories: Demorest and Walden (3) found r-values between 0.71 and 0.78 for different subscales of an adapted version of the Hearing Performance Inventory (HPI). Weinstein et al. (4) showed r-values larger than 0.90 for face to face administration of the Hearing Handicap Inventory for Elderly (HHIE), and r-values of about 0.80 for the paper and pencil format of the HHIE. Demorest and Erdman (5) found r-values between 0.58 and 0.78 for different subscales of the Communication Profile for the Hearing Impaired (CPHI). Tuley et al. (6) observed an overall test-retest reliability of 0.73 for the Quantified Denver Scale (QDS). Newman et al. (7) showed r-values ranging from 0.93 to 0.97 for the different subscales of the Hearing Handicap Inventory for Adults (HHIA). Andersson et al. (8) found an r-value of 0.70 for the Hearing Coping Assessment (HCA) inventory.

The values for the test-retest correlation, as given above, can be used to estimate the accuracy of an individual's score (see appendix 1). This information is indispensable if a hearing disability inventory is used to measure change of hearing after medical intervention, because part of the measured change is not caused by the intervention, but is the result of chance. For this reason Demorest and Walden (3) defined

an' 'interval for true change'' for inventory scores. Only individual score changes larger than this interval are very unlikely the mere result of chance. The issue of test-retest reliability of individual scores on hearing handicap inventories has been discussed for other inventories than the (m)AIAD by Weinstein et al. (4) for the HHIE, by Demorest and Erdman (5) for the CPHI, and by Newman et al. (7) for the HHIA.
The present paper deals with the reliability of the relation between change of hearing measured both audiometrically and with the (m)AIAD.

Patients and methods

Subjects

This prospective study of pre- and post-intervention hearing included 66 patients (39 male and 27 female), who underwent a tympanoplasty operation in combination with a closed or open technique mastoidectomy. All patients received an ossicular reconstruction using hydroxylapatite otologic implants adapted to the defective ossicular chain. The primary aim of the operation was to cure the affected ear. The requirements for participation were: age between 15 and 65 years, no known learning disability and no use of a hearing aid. The average age of all patients was 37 years (range: 15- 65 years). Half of the patients were operated on their right ear, the other half on their left ear. The patients were asked to participate in the study and to give informed consent.
Preoperatively (at time t_0) and three months postoperatively (at time t_1) pure-tone audiometry was performed, including air- and bone- conduction thresholds, and subjective hearing ability was established at the same times by means of the (modified) Amsterdam Inventory for Auditory Disability and Handicap (2).

Audiometry

Pure-tone audiometry was performed on all subjects. Air-conduction and bone-conduction thresholds were obtained at 0.5, 1, 2 and 4 kHz. The average hearing threshold for these 4 frequencies at t_0 and t_1 was calculated for the (to be) operated ear and for the contralateral ear. Average thresholds were rounded off at multiples of 5 dB. Improvement or regression of an individual's hearing was expressed as the change in average hearing threshold for the operated ear.

Self-reported disability

In this study, we made use of a modified version of the Amsterdam Inventory for Auditory Disability and Handicap as described in a preceding paper (2).
The modified version of the AIAD (English translation of the original version by Kramer et al. (1) in appendix 2) was handed out to all patients during their visit of the outpatient clinic, both before and three months after the operation. They were asked to fill in all questions and to return the list directly after completion. Responses to

each question were coded on a scale of 0-3; the higher the score, the smaller the perceived hearing difficulties were. The total score on the list was calculated per subject by adding the scores for the 28 questions (maximum total score: 84). The improvement or regression in hearing disability after surgical middle ear intervention was calculated by subtracting the total score at t_0 from the score at t_1 .

Results

Audiometry

Average preoperative hearing thresholds (dB HL) are given in figure 1 for the affected (to be operated) ear and for the contralateral ear, for all 66 participants. The mean threshold for the affected ear is 49.5 dB (range 15-110 dB) and 25.1 dB (range 10-85 dB) for the contralateral ear. The minimum stimulus level used for standard audiometry in our clinical setting is 10 dB HL. Figure 2 gives the change in hearing threshold for the affected ear as a result of the operation. On average the improvement of hearing level was 6.3 dB (range -25 to + 45 dB).

Self-reported disability

Figure 3 shows the individual (m)AIAD-scores pre- an postoperatively. The mean preoperative score is 50.6 (range 0-84) and the mean postoperative score is 52.0 (range 0-83).

The distribution for the preoperative (m)AIAD scores is given in figure 4.

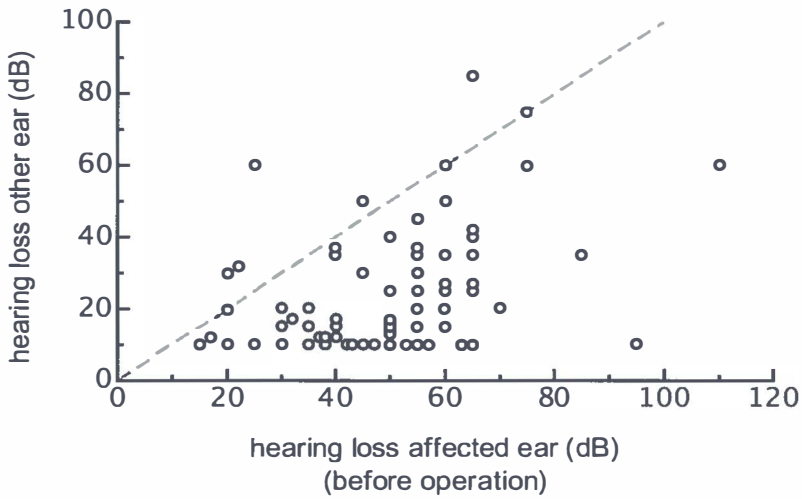

Figure 1. Hearing loss (averaged over 0.5, 1, 2 and 4 kHz) for the (to be) operated ear and for the contralateral ear for all 66 subjects. Some data-points have slightly been shifted to avoid overlap.

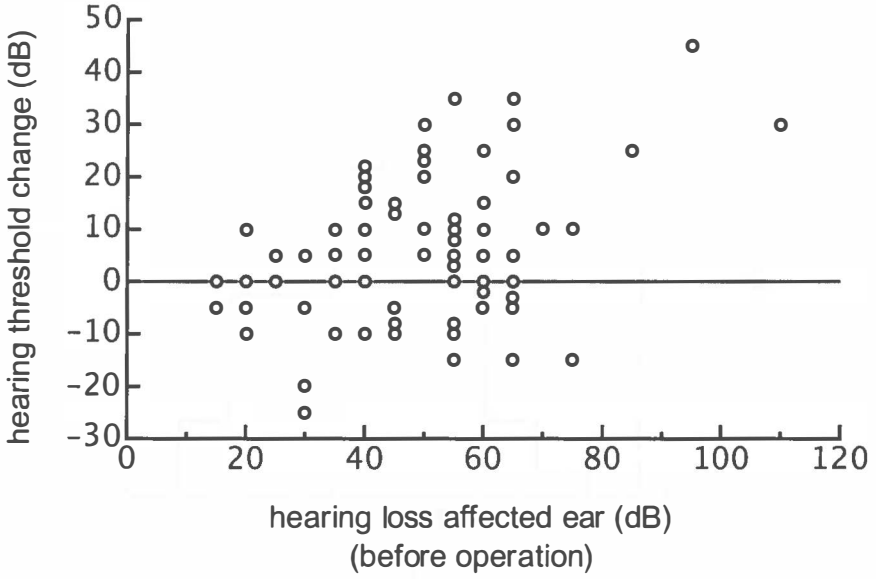

Figure 2. Horizontal axis: hearing threshold before operation (averaged over 0.5, 1, 2 and 4 kHz).Vertical axis: average hearing threshold after operation minus average threshold before operation (positive difference corresponds with improvement of hearing). Some data-points have slightly been shifted to avoid overlap.

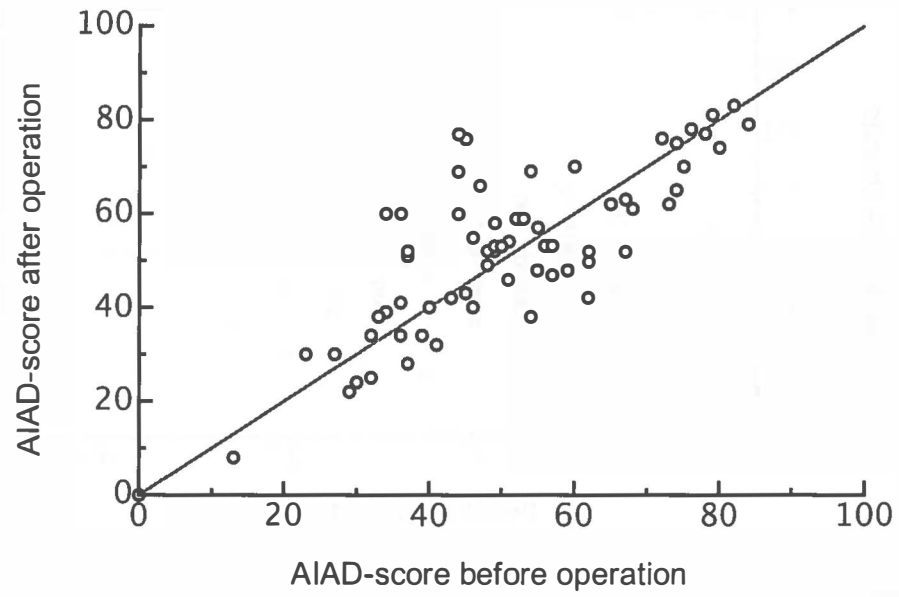

Figure 3. (m)AIAD-scores before (at t_0) and after operation (at t_1), for all 66 subjects. Equal scores at t_0 and t_1 are depicted by the grey line.

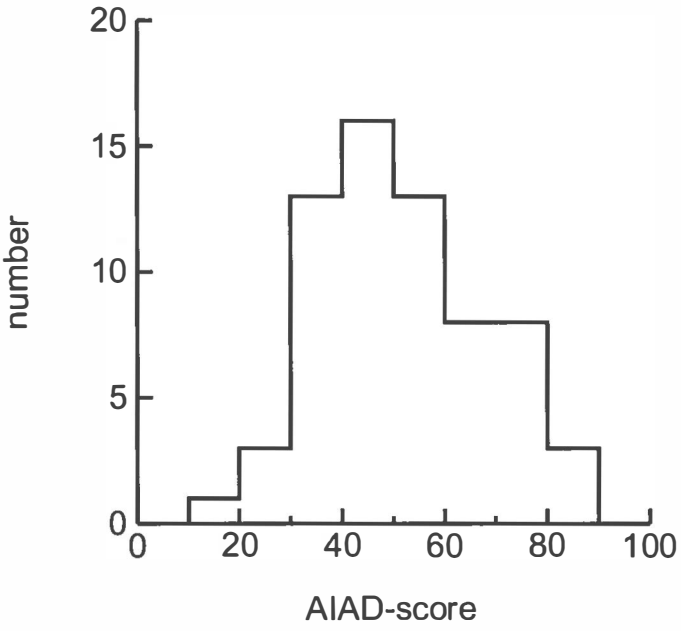

Figure 4. Distribution of (m)AIAD-scores at time t_0 (before operation).

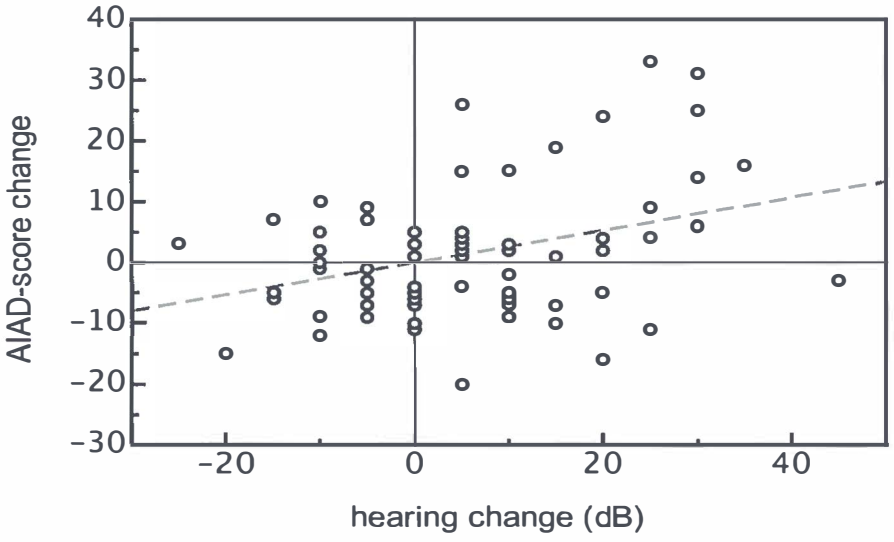

Figure 5. Difference in (m)AIAD-score before and after operation (y-axis) versus change in average hearing threshold for the operated ear (x-axis). The dashed line is a least-squares fit to the data points with equation: y = 0.266 x.

Relation between change in hearing and in self-reported disability

Figure 5 gives the relation between the change in (m)AIAD-score between times t_0 (before operation) and t_1 (after operation) and the change in hearing threshold in the operated ear, as a consequence of the operation. The correlation between score change and threshold change was found to be 0.35 (Pearson's r).

Discussion

The relation, as shown in figure 5, between hearing change and (m)AIAD score change predicts on average a score change of 8 points for a change of hearing of 30 dB. The relation between score change and hearing threshold change is not very strong (r = 0.35), but similar correlation values are found for other inventories: Lutman et al. (9) calculated correlation coefficients for the relation between components of the Hearing Disability Questionnaire (HDQ) and audiometric descriptors. The values varied between 0.30 and 0.63 if binaural average hearing thresholds, involving the frequencies 0.5, 1, 2 and 4 kHz, were considered; between 0.28 and 0.62 if only the better hearing ear was taken, and 0.34 and 0.61 for the worse hearing ear only. The lower values for r are for perceived localization ability and the higher values for difficulties in understanding everyday speech. Gatehouse (10) found values between 0.13 and 0.43 for the correlation coefficients relating between hearing threshold and different subscales of the Hearing Performance Inventory (HPI). Similar values (0.11- 0.39) were found before by Demorest and Walden (3) for the same inventory. For the correlation between total HHIA-scores (Hearing Handicap Inventory for Adults) and speech frequency pure tone averages (0.5, 1 and 2 kHz) Newman et al. (11) found a value of 0.34. When hearing loss was quantified by the high frequency pure tone average (1, 2, 4 kHz) the correlation coefficient was 0.33.

For a fixed value of the change of hearing threshold the spread in (m)AIAD-score change is large (figure 5). This is partly a consequence of the uncertainty in an individual's score, as expressed in the test-retest variation. For the (m)AIAD we did already determine the test-retest correlation (r = 0.90) in a group of 94 subjects (2). However, the distribution of scores for that population contained relatively many high scores (see figure 6), which influenced the correlation through a ceiling effect. Therefore subjects with high scores were at random removed from the population, to obtain a score distribution for the so obtained population that resembled the distribution for the population in the present study (compare figures 4 and 6 (gray area)). Test-retest correlation for this new population was 0.845, indeed somewhat smaller than the original r = 0.90. The variance in scores was 184.9 for the test and 218.9 for the retest. These numbers yield a variance of 63.8 for the difference between test and retest scores (see appendix 1; second last line). So the standard deviation for the test-retest differences is 8.0. The distribution for these differences is given in

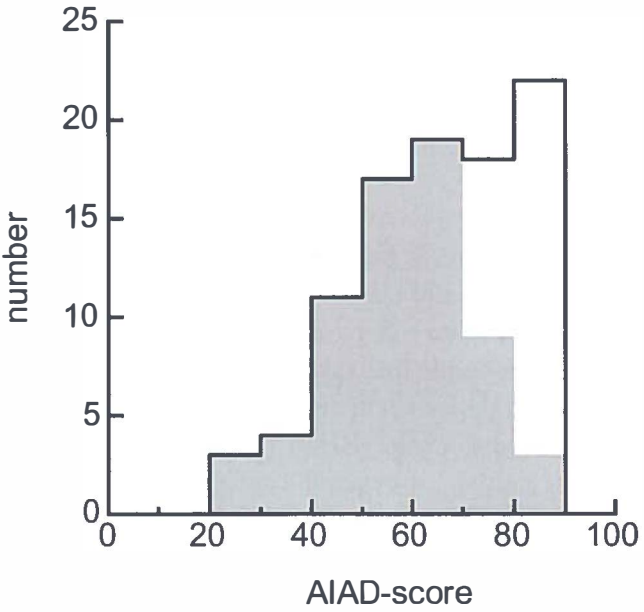

Figure 6. Black line: distribution of test scores from the population (n=94) for which the test-retest correlation was initially determined (Meijer et al.; 2002). Grey area: distribution of test-scores (to be compared with figure 4) after at random removal of 28 subjects with high scores. For the so obtained population (n=66) test-retest characteristics were recalculated.

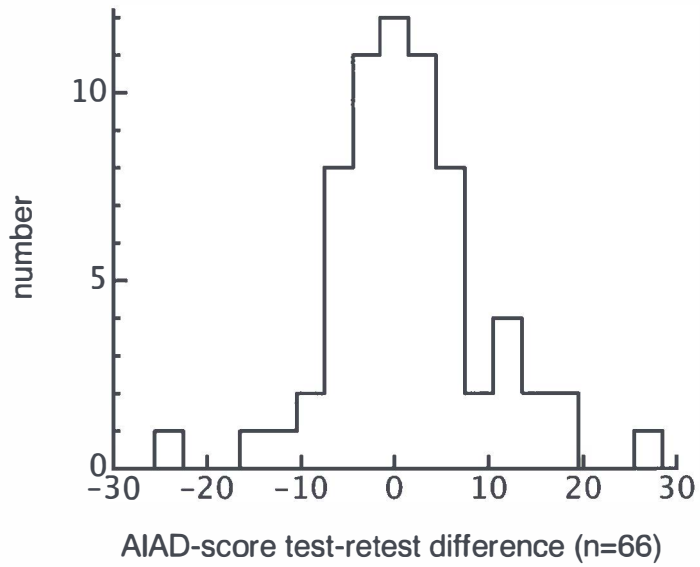

Figure 7. Distribution of test-retest differences for (m)AIAD-scores measured in a group of 66 subjects with a test-score distribution as shown in figure 6 (grey area).

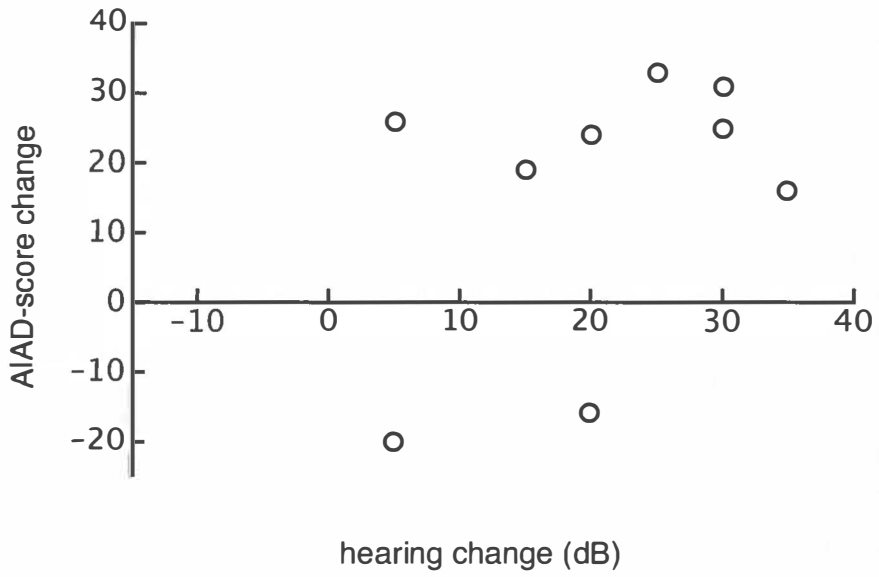

Figure 8. Relation between change in average hearing threshold and change in (m)AIAD-score for the 9 (out of 66) subjects for which a true score change was measured.

figure 7, and from this distribution the standard deviation can of course also directly be calculated. Following Demorest and Walden (3) a score difference 'interval for true change' can be defined. If the interval is taken as two standard deviations of the test-retest difference distribution, the (m)AIAD-score has to change by at least 16 (= 19 % of maximum score) to signify a true change in perceived disability. The majority of subjects, for which the relation between change in hearing loss and change in (m)AIAD-score is given in figure 5, does not fulfill this criterion.

Figure 5 is re-plotted as figure 8 for only those subjects for which a true score change was measured. It can be concluded from this figure that the true score changes occur mainly for subjects who's hearing loss decreased as a result of the operation, but a less global relation between score change and hearing change cannot be derived from figure 8.

It must be concluded that most (m)AIAD-score changes were not large enough to quantify them as true changes. This illustrates that disability questionnaires have their limitations, when using them to measure the result of a medical intervention in an individual patient. As the test-retest variability of the (m)AIAD is not worse than that for other questionnaires, the above statement also holds for other inventories.

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Appendix 1: Variance of difference between individual test and retest scores.

Consider n pairs of numbers (x, y), in which for the present purpose x_i and y_i are test and retest scores respectively.

De difference between test en retest results is given by $d = y - x$.

The *covariance* is defined as: $\sigma_{xy} = \frac{\Sigma(x-\bar{x})(y-\bar{y})}{n}$,

the *variance* of x as: $\sigma_x^2 = \frac{\Sigma(x-\bar{x})^2}{n}$, with a similar definition for the variances of y and d.

The *correlation* between x and y can then be calculated with: $r_{xy} = \frac{\sigma_{xy}}{\sigma_x \sigma_y}$.

It can straightforwardly be shown that the variance of x can be calculated with:

$\sigma_x^2 = \frac{1}{n}\Sigma x^2 - \bar{x}^2$. Similar for y and d and $\sigma_{xy} = \frac{1}{n}\Sigma xy - \bar{x}\bar{y}$.

Combining these relations and substituting $d = y - x$ gives:

$\sigma_d^2 = \frac{1}{n}\sigma_d^2 - \bar{d}^2 = \frac{1}{n}\Sigma y^2 + \frac{1}{n}\Sigma x^2 - 2\frac{1}{n}\Sigma xy - \bar{d}^2 =$

$\sigma_y^2 + \bar{y}^2 + \sigma_x^2 + \bar{x}^2 - 2\sigma_{xy} - 2\bar{x}\bar{y} - \bar{d}^2 =$

$\sigma_y^2 + \sigma_x^2 - 2\sigma_{xy} + (\bar{y} - \bar{x})^2 - \bar{d}^2$.

So $\sigma_d^2 = \sigma_y^2 + \sigma_x^2 - 2\sigma_{xy} = \sigma_y^2 + \sigma_x^2 - 2r_{xy}\sigma_y\sigma_x$.

For $\sigma_y = \sigma_x = \sigma$ this can be written as $\sigma_d^2 = 2\sigma^2(1 - r_{xy})$.

Appendix 2: The Amsterdam Inventory for Auditory Disability and Handicap

1 Can you understand a shop assistant in a crowded shop?
2 Can you carry on a conversation with someone in a quiet room?
3 Do you immediately hear from what direction a car is approaching when you are outside?
4 Can you hear cars passing by?
5 Do you recognize members of your family by their voices?
6 Can you recognize melodies in music or songs?
7 Can you carry on a conversation with someone during a crowded meeting?
8 Can you carry on a telephone conversation in a quiet room?
9 Can you hear from what corner of a lecture room someone is asking a question during a meeting?
10 Can you hear somebody approaching from behind?
11 Do you recognize a presenter on TV by his/her voice?
12 Can you understand text that's being sung?
13 Can you easily carry on a conversation with somebody in a bus or car?
14 Can you understand the presenter of the news on TV?
15 Do you immediately look in the right direction when somebody calls you in the street?
16 Can you hear noises in the household, like running water, vacuuming, a washing machine?
17 Can you discriminate the sound of a car and a bus?
19 Can you follow a conversation between a few people during dinner?
20 Can you understand the presenter of the news on the radio?
21 Can you hear from what corner of a room someone is talking to you being in a quiet house?
22 Can you hear the door-bell at home?
23 Can you distinguish between male and female voices?
24 Can you hear rhythm in music or songs?
25 Can you carry on a conversation with someone in a busy street?
26 Can you distinguish intonations and voice inflection in people's voices?
27 Do you hear from what direction a car horn is coming?
28 Do you hear birds singing outside?
29 Can you recognize and distinguish different musical instruments?

Excluded items

18 Do you experience that music is too loud for you, while others around don't complain about the loudness?
30 Do you miss parts of music while listening to music or songs?

Each question is divided into 3 parts, which all refer the to same situation.
In the A-part the respondent is asked to judge how he/ she experiences auditory difficulties in the mentioned situation. Subjects are asked to respond on the basis of their experiences without a hearing aid.
In the B-part the respondent is asked to judge how he/ she experienced the auditory difficulty in the mentioned situation in the past.
In the C-part the respondent is asked to judge how handicapped he/ she feels by having difficulties in hearing in the mentioned situation.

In the A- and B- part of the inventory the 4 answer categories are as follows: almost never- occasionally- frequently- almost always. In the C-part the 4 answer categories are: no- slightly- moderately- considerably.

Chapter 9

Evaluation of the relation between audiometric and psychometric measures of hearing after tympanoplasty.

AGW Meijer, HP Wit, FWJ Albers.
Evaluation of the relation between audiometric and psychometric measures of hearing after tympanoplasty.
Submitted.

INTRODUCTION

The results of reconstructive middle ear surgery in the otological literature are traditionally reported by postoperative closure of the air-bone gap and improvement of the air-conduction thresholds in dB HL of the operated ear. These parameters are a reflection of the technical success of middle ear reconstruction, restricted to monoaural hearing disability. It does not evaluate the effect of surgery on binaural hearing ability, reflecting subjective hearing. Not infrequently a clinician becomes aware of a discrepancy between the post-operative improvement of the audiometric thresholds and the patient's opinion of their hearing capacities as mentioned by several authors (1-17).
In 1985 the Belfast Rule of Thumb (13) and in 1991 the Glasgow Benefit Plot (14) were introduced to predict and measure patient hearing benefit in reconstructive middle ear surgery. Both methods are based on the idea that patient benefit includes more than the change in air-bone gap or decrease in air-conduction threshold. Hearing benefit depends on the final absolute value of hearing in the operated ear, as well as on its relationship to the hearing in the contralateral ear. According to the "Rule of Thumb" patient benefit is achieved when the mean postoperative air-conduction threshold (for 0.5 to 4 kHz) in the operated ear is at most 30 dB HL or when the postoperative inter-aural difference is not larger than 15 dB HL. In the Glasgow Benefit Plot the pre- and postoperative values for the air-conduction thresholds in both ears are used to evaluate binaural hearing results. Potential patient benefit is in this method represented in four different postoperative categories: a: binaural normal hearing, b: unilateral normal hearing, c: the operated ear improves, but is still impaired, d: symmetric, but still impaired thresholds. The postoperative categories a and b are considered to represent patients with the most significant patient benefit, while the categories c and d are regarded as less beneficial.
Both methods are based on the principle that an individual ear only contributes to hearing if the threshold of the individual ear is better than a critical value often defined as 30 dB HL (2,4,6,7,10-16). If only one ear is operated the non-operated ear is in most cases the better hearing ear. Unless the proposed surgery can restore symmetrical hearing or convert the operated ear into the better ear, the patient is unlikely to experience a reduction in hearing disability. Symmetrical hearing is defined as an inter-aural difference of at most 15 dB HL (4-16). The Glasgow Benefit Plot (14) or other criteria for the prediction of patient benefit were introduced to prevent too optimistic advices for reconstructive middle ear surgery.

Hearing disability can be measured either by performance testing or by self report. Pure-tone audiometry alone, as demonstrated by various investigators (18-27) is a moderate predictor of difficulties experienced subjectively in daily life listening. It

is common experience in otological clinical practice that individuals with the same audiometric thresholds can experience quite different degrees of hearing difficulties. To obtain insight in hearing quality, self-assessment measures of hearing ability, along with performance measures, can be used successfully as has been shown by several authors (18-27). However, questionnaire responses are prone to bias from factors like exaggeration, personal opinion and inappropriate self perception (18-26). Furthermore, the applicability of a self-assessment questionnaire to individual patients is limited by test-retest variability (28-31).
The present study evaluated the relation between audiometric and psychometric measures after tympanoplasty in the perspective of pre-operative selection of patients and postoperative assessment of the results of reconstructive middle ear surgery.

Patients and methods

In this prospective study 103 patients were included, who underwent a tympanoplasty operation in combination with a closed or open technique mastoidectomy in a tertiary referral center (University Hospital Groningen). Many patients were operated previously and suffered from chronic otitis media and mastoiditis or cholesteatoma. Modified radical mastoidectomy had been performed at an earlier date in 15 ears. All patients received an ossicular chain reconstruction with hydroxylapatite otologic implants adjusted to the defective ossicular chain (Smith and Nephew Richards Inc) and chosen from 4 basic types of prostheses as given in Table 1. A cartilage plate with a thickness of 0.4 or 0.5 mm was interposed between the head of the prosthesis and the inner surface of the tympanic membrane to prevent extrusion of the prosthesis (32,33).
Further requirements for participation in the study were age between 15 and 65 years, no known learning disability and no (continuous) use of a hearing aid. The average age of all patients was 37 years (range 15-65, 61 male and 42 female patients). In 54 patients the right ear was operated, in 49 the left ear. All patients were asked to participate in the study, and gave their informed consent.
Preoperatively and at three and twelve months post-operatively air and bone-conduction thresholds were measured at 0.5, 1, 2 and 4 kHz. Average pure-tone air and bone-conduction thresholds were calculated as the mean of the 0.5, 1, 2 and 4 kHz values for each ear separately and rounded off at multiples of 5 dB. In the following text the operated ear will be called "ipsilateral" and the non-operated ear "contralateral". The air-bone gap in the ipsilateral ear, averaged over all patients, was 23 (±14 dB) before operation.
The subjective hearing ability of all participants was established pre-operatively and at three and twelve months post-operatively by means of a validated questionnaire: the (modified) Amsterdam Inventory for Auditory Disability and handicap ((m)AIAD) (28,34). Responses to each question were coded on a scale from 0 to

3; the higher the score, the smaller the perceived hearing difficulties were. The total score per subject was obtained by adding the scores for all 28 questions of the questionnaire (maximum total score: 84). Subjects were asked to respond to all questions on the basis of their experiences without a hearing aid.
In all cases but 5, the worse or equally (inter-aural difference ≤5 dB) hearing ear was operated. Statistical analyses were performed using Statistical Package for the Social Sciences (SPSS, version 8.0). Results were regarded to be statistically significant at p-values ≤0.001.

Results

Of the initial 103 participants 99 were evaluated at 3 months and 80 at 12 months after the operation. Reasons for drop out during the study were: continuous use of a hearing aid after the operation, intervenient implantation of a bone anchored hearing aid (BAHA), or incompleteness of answers and/or audiometric data. Of the 103 tympanoplasties with ossicular chain reconstruction 4 extrusions were noticed and 3 prostheses were is a definite phase of protrusion. No systematic difference in ipsilateral air conduction improvement was found between 3 and 12 months after the operation (correlation between thresholds at 3 and 12 months: 0.84, p≤ 0.001). Furthermore, there was no systematic difference in total individual scores on the AIAD after 3 and 12 months (correlation between scores at 3 and 12 months post-operatively: 0.89, p≤ 0.001). Therefore and for the reason that results at one year provide a more realistic guide to patient counseling than short term results (35), further quantitative analysis of the hearing data was restricted to the 12 months results.

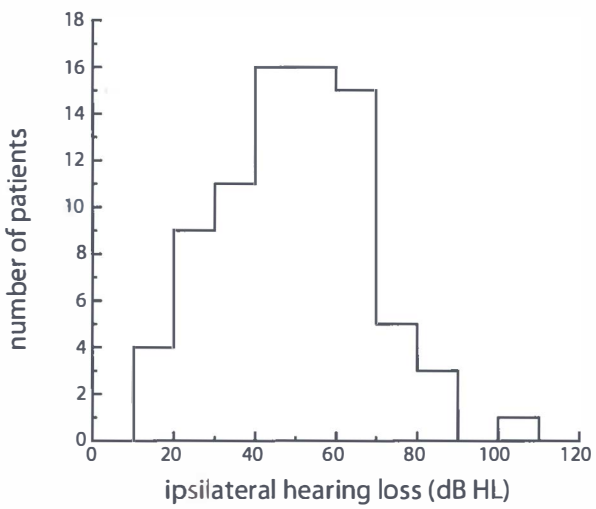

Figure 1. Distribution of ipsilateral air conduction hearing losses before operation in dB HL, for the total group of 80 patients that were evaluated after one year.

Figure 1 shows the distribution of the ipsilateral hearing losses before operation in dB HL for the total group of 80 patients that were evaluated after one year.
Figure 2 shows the change in hearing in the operated ear for this total group. The average improvement of the air conduction threshold in the operated ear was 5.4 (± 14.3) dB. In thirty eight ears (48 %) hearing levels improved, while 21 ears (26 %) showed unchanged hearing levels and another 21 ears (26 %) showed worse hearing after the operation. As expected, contralateral air conduction thresholds were stable, with an average value of 25.1 dB HL pre-operatively as well as post-operatively, and a standard deviation of 16 dB. Mainly due to measurement inaccuracies the standard deviation in average individual contralateral air conduction threshold changes was 5.3 dB.

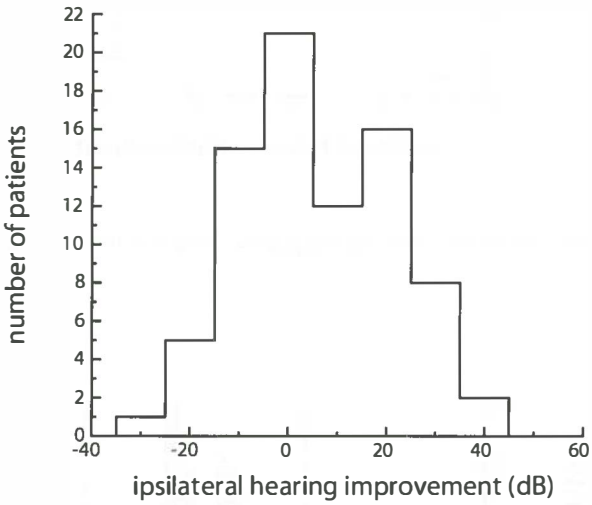

Figure 2. Distribution of the change in hearing in the ipsilateral ear, as a result of the operation, for the total group of 80 patients that were evaluated after one year.

In Figure 3 the individual preoperative (m)AIAD-scores are plotted against the ipsilateral pre-operative hearing losses in dB HL.
Figure 4 gives the distribution for the improvement after one year of the (m)AIAD-scores for the whole patient population. This improvement was on average 2.9 points, with a standard deviation of 12.1 and a standard error of the mean of 1.4. It can be concluded from these numbers that the improvement is significant. Forty six patients (58 %) showed an improvement in total score on the (m)AIAD, 2 patients (2 %) showed an unchanged total score on the (m)AIAD and 32 patients (40%) showed worse total scores on the (m)AIAD post operatively.
The interval for true change of the (m)AIAD was established in an earlier study (28) with the result that individual scores on the (m)AIAD had to change by at least 16

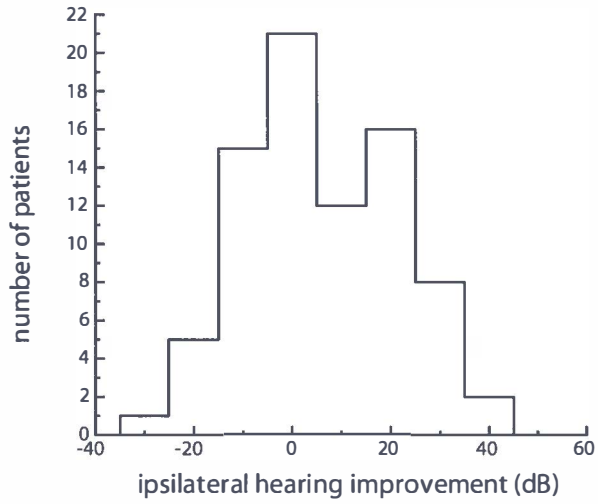

Figure 3. Preoperative (m)AIAD-scores plotted against ipsilateral air conduction hearing losses in dB HL for all 80 patients.

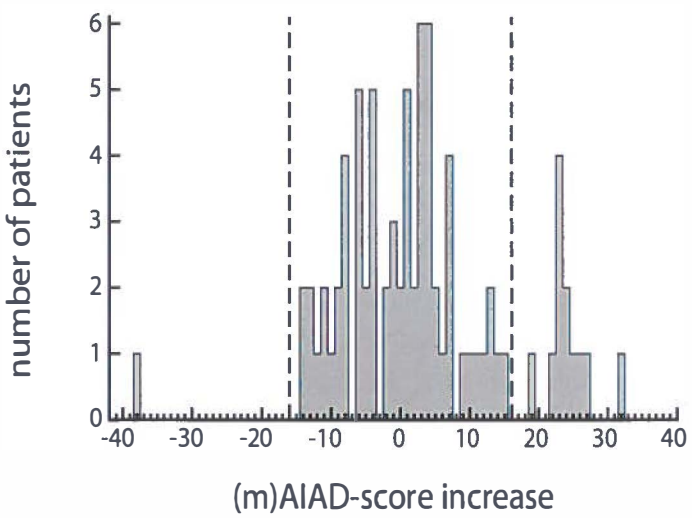

Figure 4. Distribution for the (m)AIAD-score after operation minus the score before operation for all 80 patients

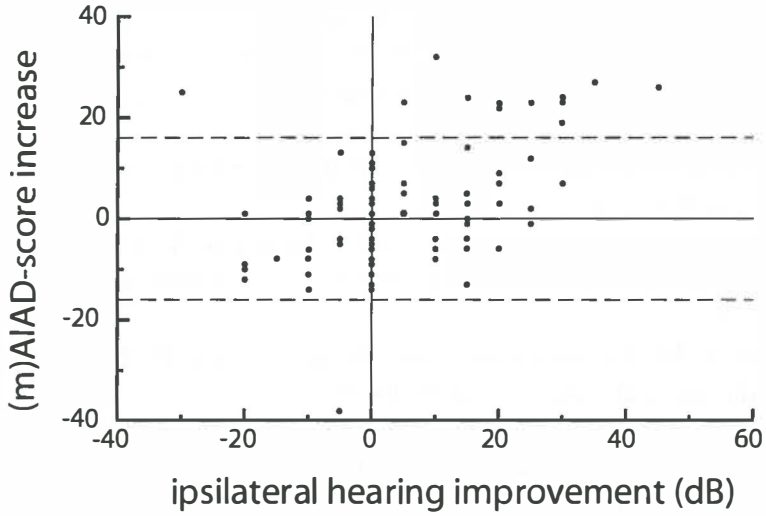

Figure 5. The relation between (m)AIAD-score increase (as shown in figure 4) and ipsilateral hearing improvement (as shown in figure 2) for all 80 patients. Between the horizontal dashed lines score change is too small, due to test-retest variability, to be a true change.

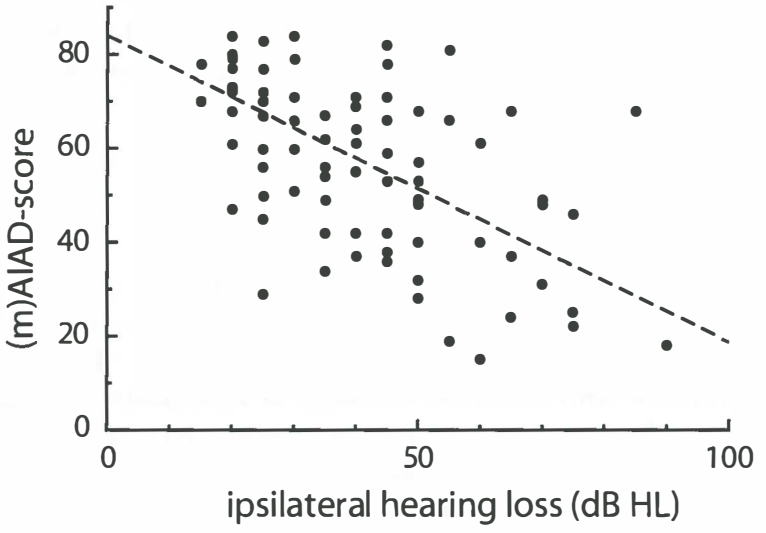

Figure 6. Relation between air conduction hearing loss in dB HL of the ipsilateral ear and the (m)AIAD-score, both after operation, for all 80 patients. The slope of the dashed line (least squares fit) is - 0.65 points/dB.

points to be qualified as a true change in perceived hearing disability. The interval for true change (-16, 16) is indicated in Figure 4 by two vertical dashed lines. Taking this interval for true change into consideration, 67 patients (84%) showed no true change. One patient showed a true worsening of the (m)AIAD-score and 12 patients (15%) showed a true score improvement after intervention.
The relation between (m)AIAD-score increase and ipsilateral hearing improvement in dB HL is shown in Figure 5. In about 1/3 of the patients the score improved while hearing became worse or vice versa.
Figure 6 shows the relation between air conduction hearing loss of the operated ear and the (m)AIAD-score after operation. The slope of the fitted dashed straight line in the figure is
-0.65 points/dB. Higher order curves did not give a better fit. The correlation between hearing loss and score is -0.54 (Pearson's r).
The same procedure for post-operative (m)AIAD-score and contralateral air conduction threshold yielded a correlation coefficient of -0.37.
A somewhat stronger correlation (r = -0.63) is obtained when the (m)AIAD-score after operation is plotted against the air conduction threshold after operation averaged over both ears (figure 7). The dashed line in Figure 4 has a slope of 0.87 points/dB. Two "outliers" (open circles in figure 7) were not taken into account in the calculations.
The data in Figure 7 were grouped in 10 dB wide intervals in two ways (11-20, 21-30.....and 10-15, 16-25, 36-45.....) and the average loss, the average score and the standard error of the average score were calculated per group. The result is given in Figure 8. The dashed line in this figure (a fit with the sum of a gaussian curve and the derivative of a gaussian curve) is merely meant to guide the eye.

Discussion

The average ipsilateral hearing improvement of all 80 patients as the result of reconstructive middle ear surgery, evaluated at 12 months post-operatively, was 5.4 dB as shown in Figure 2, with a large spread in individual results. Almost all patients suffered from chronic otitis media and mastoiditis or cholesteatoma and underwent a revision open or closed mastoidectomy in combination with tympanoplasty, which can explain the limited improvement of hearing.
The limited improvement in hearing after reconstructive middle ear surgery may also explain the rather small increase in (m)AIAD-score (on average 2.9 points), as represented in Figure 4. Due to this limited change in (m)AIAD-score after operation, the majority of patients does not produce a change in (m)AIAD-score outside the interval for "true change"(28), as indicated by the dashed straight lines in Figures 4 and 5.

Although not very strong audiometric improvement and increase in (m)AIAD-score are related, as shown in Figure 5.

A general and serious problem when using self-report questionnaires is the relatively large test-retest variability and the consequences thereof for the interpretation of individual score-changes (28-31). The vertical position, for instance, of the individual points in Figure 5 has a large uncertainty.

The expected (significant) correlation between (m)AIAD-score after operation and the resulting hearing loss of the operated ear is demonstrated in Figure 6. Lower scores on the (m)AIAD are related to a larger remaining hearing losses. This correlation is somewhat larger when the post operative (m)AIAD-scores are plotted against hearing loss after the operation averaged over both ears (see Figure 7).

The set of data points in Figure 7 show little structure. However, when mean scores are calculated for different 10 dB-intervals, as represented in Figure 8, an interesting relation between mean (m)AIAD-scores and mean hearing losses (averaged over both ears) emerges: The (m)AIAD-score is almost independent of hearing loss for postoperative hearing levels between 25 and 40 dB. Residual hearing loss has to become smaller than 25 dB, before better hearing corresponds with a higher (m)AIAD-score. For losses larger than 40 dB the (m)AIAD-score clearly decreases with increasing hearing loss.

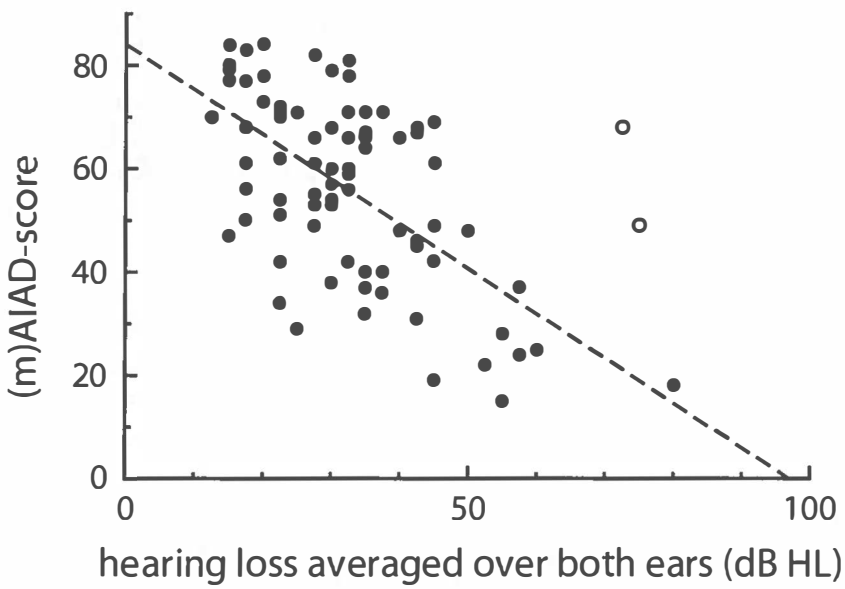

Figure 7. Relation between air conduction hearing loss averaged over both ears in dB HL and the (m)AIAD-score, both after operation, for all 80 patients. The slope of the dashed line (least square fit) is -0.87 points/dB. (The two open circles are "outliers" that were not taken into account for the fit.)

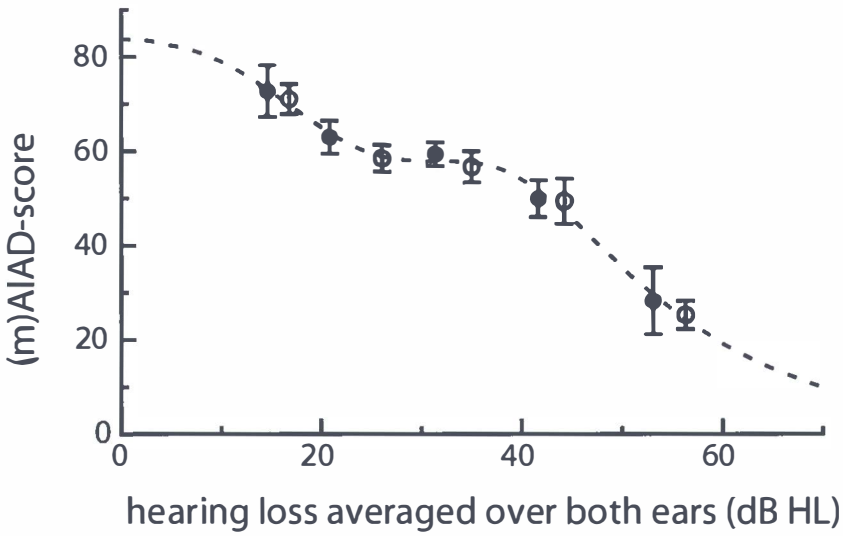

Figure 8. Figure 7 re-plotted after grouping of the data in 10 dB intervals, as described in the Results section. Vertical line segments denote standard errors of the mean. The dashed line is a least squares fit (see text for explanation).

Because Smyth and Patterson (13) state that the contralateral ear is (near) normal in the patient group that they investigated, their "Rule of Thumb" (see Introduction section) is not in conflict with the results shown in Figure 8: Patients with an operated ear that has reached an air conduction of 30 dB HL or better or has come within 15 dB of the contralateral ear will have an estimated threshold that is better than about 20 dB, when it is averaged over both ears. Figure 8 shows that the best (m)AIAD-scores are obtained for the smallest residual losses.

For hearing losses smaller than 25 dB (m)AIAD-scores are between 60 and 70 in Figure 8. This is still rather far below the maximum score of 84, as obtained for subjects without any hearing difficulty, which means that even small residual losses lead to perceived disability. This finding is supported by Nia and Bance (36), who showed that even small unilateral conductive losses lead to a significant disadvantage in word recognition at low signal to noise ratios or low presentation volumes. They conclude that the benefits of surgery to improve hearing do not depend only on the degree of hearing improvement, but also on the final hearing threshold in both ears.

In contrast with the conclusion that good hearing in both ears is a prerequisite for high patient satisfaction are results obtained by Browning (9). He measured a high average score on the Glasgow Benefit Inventory in a group of patients for whom the hearing loss, averaged over both ears after operation, was still 55 dB HL. These patients had a bilateral, asymmetric impairment before surgery. The operation had turned the

operated ear into the better hearing ear. In contrast, a rather low benefit score was obtained for a group of patients who had a unilateral impairment before operation an in whom the operated ear had "normal "thresholds after surgery. Hearing loss after operation for this group was only 22 dB HL (averaged over both ears).
The deviation of Browning's results, and presented as "Glasgow Benefit Plots" (9, fig.10-18), from the results summarized in our figure 8, may be a consequence of the difference in questionnaires that were used to measure subjective hearing. The Glasgow Benefit Inventory (18 questions) inquires about a change in health subsequent to surgery, while the (m)AIAD (28 questions) was used to measure hearing ability, both before and after operation. For a reliable comparison of methods that classify results of middle ear surgery, not only the ways in which (objectively measurable) hearing loss before and after surgery is presented should be compared, but also the questionnaires that were used to quantify subjective (change of) hearing.

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Chapter 10

Summary and Conclusions

Summary

This thesis concerns modern aspects of tympanoplasty in which success or failure is mainly determined by two different entities: the technical dimension and the functional dimension. Important technical aspects of tympanoplasty are the evolution of microsurgical techniques, the importance of eustachian tube function, grafts used for reconstruction of the tympanic membrane and the ossicular chain, and the introduction of biomaterials for implantation purposes. Important functional aspects of tympanoplasty are the assessment of disability or handicap experienced by an individual due to hearing impairment, not only for clinical management and rehabilitation purposes, but also for employment and medico-legal related issues.
In this thesis the first part is concentrated on the highly relevant issue of the technical dimension in reconstructive middle ear surgery: the aspects of biocompatibility of synthetic middle ear implants.
The second part of the thesis is focused on the functional dimension in reconstructive middle ear surgery: the assessment of the hearing (dis)ability in the normal and hearing impaired individual.

Chapter 2 gives an overview of the literature concerning the technical and functional dimensions in reconstructive middle ear surgery. The literature regarding the technical dimension is focused on the historical development of reconstructive middle ear surgery, on middle ear mechanics and biocompatibility of implant material. The literature review with regard to the functional dimension includes the assessment of hearing by means of pure-tone audiometry and self-assessment questionnaires.

Technical dimension of reconstructive middle ear surgery

Chapter 3 describes the results of cartilage interposition between a hydroxylapatite middle ear prosthesis and the tympanic membrane with regard to the extrusion process of the implant in guinea pigs. With the introduction of the highly biocompatible calcium phosphate ceramics (for example hydroxylapatite), rejection due to a foreign body reaction to the material is seldom observed anymore. However, extrusion of a ceramic middle ear implant may still happen when the implant is in direct contact with the tympanic membrane. In these cases extrusion is probably not caused by a foreign body reaction to the implant, but by pressure necrosis of the tympanic membrane.
In this study, two groups of guinea pigs are examined. One group consists of animals in which a hydroxylapatite middle ear prosthesis is directly in contact with the tympanic membrane, the other group consists of animals in which a cartilage disc has

been inserted between the head of the hydroxylapatite prosthesis and the tympanic membrane. Light and transmission electron microscopical examinations were performed. We studied the histopathological aspects of the tympanic membrane with regard to the protrusion and extrusion processes of the middle ear implant. In this experimental model, protrusion and extrusion of a hydroxylapatite middle ear prosthesis is greatly reduced by interposition of a cartilage disc.

In Chapter 4 we introduce a new instrument for tympanoplasty: The Groningen Cartilage Cutting Device. For many years, otologic surgeons have successfully used biocompatible synthetic materials in tympanoplasty to reconstruct the middle ear sound conduction system. For all these synthetic implants, the intrinsic problems were rejection and extrusion. As described in the experimental study in Chapter 3, extrusion rates can be lowered by interposing a small cartilage disc between a synthetic implant and the tympanic membrane. Cartilage interposition can interfere with the mechanical properties of the sound-conducting mechanism of the middle ear if the cartilage disc is too thick. However, if the cartilage disc is too thin, extrusion may not be prevented. In this chapter we describe a standard method of producing a cartilage disc that is thin enough not to interfere with the mechanical properties of the sound-conducting mechanism, yet thick enough to prevent extrusion of the synthetic prosthesis. In our opinion, the Groningen Cartilage Cutting Device significantly contributes to tympanoplasty by providing a method for producing standardized discs used for interposition, reducing operating time otherwise needed for trimming and shaping the interposition transplant, and having proven to be an instrument that is simple and easy to use intraoperatively.

Chapter 5 describes the evaluation of the biocompatibility of hydroxylapatite-polyethylene composite implants (HAPEX, Entermed). Because of its high biocompatibility hydroxylapatite is one of the most frequently used implant materials at the moment. Implants in the middle ear cavity become rapidly covered by an epithelial and fibrous layer, without signs of a foreign body reaction, suggesting optimal biocompatibility of hydroxylapatite. However, hydroxylapatite is technically difficult to manipulate intraoperatively, as it is brittle and shatters easily when drilled or trimmed with sharp instruments. As a supplement for the hydroxylapatite shaft, polyethylene is considered as additional material for the design of middle ear prostheses. Polyethylene is easy to trim and to use intraoperatively. Polyethylene behaves as a biocompatible material. However, when in contact with the tympanic membrane, the material becomes surrounded by macrophages and foreign body giant cells indicative of rejection. In combining biocompatibility and ease of manipulation, a homogeneous material consisting of 40 % hydroxylapatite and 60 % polyethylene was introduced (HAPEX, Entermed). This composition is a biocompatible material reflecting the

mechanical properties of cortical bone, yet is soft enough to be cut with a knife. In addition, sound conducting properties benefit from the rigidity of the hydroxylapatite-polyethylene shaft material. The HAPEX middle ear prostheses consist of a hydroxylapatite head and a hydroxylapatite-polyethylene shaft.
In this study eleven HAPEX middle ear prostheses, removed during revision surgery, have been examined by light microscopy, transmission electron microscopy and scanning electron microscopy. The results show that the middle ear prostheses become overgrown by fibrous tissue inside a thin epithelial layer. In some cases the prosthesis is covered by fibrous tissue without an outer layer of epithelial cells. No indications have been found for the accumulation of macrophages and foreign body giant cells associated with a foreign body reaction to the material. Therefore, hydroxylapatite-polyethylene composite implants (HAPEX, Entermed) seem to be very suitable for reconstructive middle ear surgery.

Functional dimension of reconstructive middle ear surgery

Chapter 6 describes the results of a pilot-study investigating ways for the assessment of hearing impairment after reconstructive middle ear surgery. In the otological literature, the results of middle ear surgery are frequently reported as closure of the air-bone gap and improvement of the air-conduction threshold in dB HL. These parameters are a reflection of the technical success, but do not evaluate the effect of surgery on binaural hearing. In the literature two methods have been proposed for predicting patient benefit after reconstructive middle ear surgery: the Rule of Thumb and the Glasgow Benefit Plot. Both methods are based on an arbitrarily chosen cut-off level of 30 dB HL for socially acceptable hearing. However, reliable preoperative prediction of patient benefit can only be made after validation of this definition of socially acceptable hearing. This can be performed by means of a questionnaire measuring hearing disability as an addition to pure-tone audiometry.
In this study, we found a relationship between the degree of the subjective hearing ability measured by a hearing questionnaire and air-conduction thresholds. Further validation of the cut-off level of 30 dB HL for social acceptable hearing and further evaluation of the psychometric aspects concerning the assessment of hearing after tympanoplasty should be performed in a larger prospective study.

In Chapter 7 the investigation of the psychometric adequacy of the (modified) Amsterdam Inventory for Auditory Disability and Handicap ((m)AIAD) is reported. The AIAD is a self-assessment questionnaire that consists of 30 questions covering all the relevant disability factors of individual hearing in daily life (Kramer et al., 1995).
In this study the clinical utility of the instrument was investigated with emphasis on internal and external validity and other statistical aspects. The study reports data

from 94 subjects, aged 17-65, with different hearing ability, who completed a modified version of the AIAD on two occasions with a one-month interval. The obtained scores on the (m)AIAD are correlated with scores on a previously validated questionnaire; the Hearing Disability Questionnaire (HDQ). The psychometric adequacy of the AIAD is determined by measuring its reliability and validity. Factor analysis is performed and reliability is tested by measuring internal consistency, split-half correlation and test-retest reproducibility. The validity is tested by measuring construct and criterion validity. The results show that the reliability of the (m)AIAD is satisfactory with good internal consistency, with high split-half correlations and with high test-retest correlations. Construct validity shows a high correlation between scores on the (m)AIAD and scores on the HDQ. Criterion validity shows a moderate but significant correlation between scores on the (m)AIAD and hearing thresholds in dB HL, which is in agreement with data of other questionnaires as reported in the literature. This result does not show any inadequacy of self-assessment, but may be interpreted as a limitation in comparing audiometric data with the individual responses to self-assessment questionnaires. In conclusion, the psychometric adequacy of the (m)AIAD is tested by measuring reliability and validity. Both are satisfactory. The results of the present analysis indicate that the (m)AIAD is a promising and reliable tool in the assessment of hearing impairment in daily life.

Chapter 8 describes the evaluation of the test-retest distributions and the interval for true score change of the (modified) Amsterdam Inventory for Auditory Disability and Handicap, when the latter is used to measure the effect of an intervention. In Chapter 7 the reliability and validity of the (m)AIAD in a cohort of hearing impaired patients were found to have satisfactory high values, indicating that the (m)AIAD is a promising and reliable tool for the assessment of hearing impairment. However, a hearing disability instrument must also be statistically proven valid for measuring changes in hearing ability, when hearing thresholds change as a result of intervention.
In this prospective study, 66 patients underwent reconstructive middle ear surgery. Preoperatively and postoperatively pure-tone audiometry was performed, and at the same time the subjective hearing ability was established by means of the (m)AIAD. To determine if surgical intervention has improved the communication performance, it is necessary to determine whether the observed change in the individual score on the (m)AIAD is larger than would be expected without intervention. The results of this study population show a test-retest correlation of 0.85. The correlation between threshold change and score change is 0.35 (Pearson's r). Further statistical analysis shows that the scores on the (m)AIAD have to change by at least 16 points to be qualified as a true change. For only 9 out of 66 subjects this criterion is fulfilled. No clear relation exists, except for these 9 subjects, between threshold change and score change in this patient population. This study shows that the (m)AIAD also has limi-

tations, when used to measure the result of a medical intervention in an individual patient, despite its satisfactory psychometric adequacy (tested by measuring the reliability and validity).

In Chapter 9 the relation between audiometric and psychometric measures after tympanoplasty is evaluated in the perspective of pre-operative selection of patients and post-operative assessment of the results of reconstructive middle ear surgery. Hearing (dis)ability is measured by means of pure-tone audiometry and a validated self-assessment questionnaire: the (modified) Amsterdam Inventory of Auditory Disability and Handicap ((m)AIAD). Average hearing thresholds and (m)AIAD-scores are evaluated for 80 patients, pre- and 12 months postoperatively.
The average improvement of the air conduction threshold in the operated ear is 5.4 (14.3) dB; the average improvement in (m)AIAD- score is 2.9 points (12.1). Although not very strong, audiometric improvement of hearing and increase in (m)AIAD-score are significantly related.
After the calculation of postoperatively measured mean scores on the (m)AIAD for different 10 dB-intervals of postoperative hearing loss averaged over both ears, an interesting relation between (m)AIAD-score and hearing losses emerges: The (m)AIAD-score is almost independent of hearing loss for postoperative hearing levels between 25 and 40 dB. Residual hearing loss has to become less than 25 dB, before a smaller hearing loss corresponds with a higher (better) (m)AIAD-score. For losses larger than 40 dB the (m)AIAD-score clearly decreases with increasing hearing loss. Finally, even small residual hearing losses lead, on average, to (m)AIAD-scores that are substantially lower than the score for normal hearing subjects.

Conclusions

Technical dimension of reconstructive middle ear surgery

Protrusion and extrusion of hydroxylapatite middle ear prosthesis (in guinea pigs) is greatly reduced by interposition of a cartilage disc between the tympanic membrane and the head of the prosthesis.
Use of the Groningen Cartilage Cutting Device can improve tympanoplasty by providing a method for producing standardized cartilage discs used for interposition between a synthetic middle ear prosthesis and the tympanic membrane.
Hydroxylapatite-polyethylene composite implants (HAPEX, Entermed) have very good biocompatibility, when positioned in the middle ear cavity between the tympanic membrane and the stapes or stapes-footplate. No accumulation of macrophages and giant cells, indicative for foreign body reactions, are observed when this implant material is used.

Functional dimension of reconstructive middle ear surgery

In the otological literature social acceptable hearing is often defined by a maximum loss of 30 dB HL. This critical value is based on the results of two studies reconsidering the parameters for evaluating benefits from middle ear surgery ("the Rule of Thumb" and "the Glasgow Benefit Plot"). According to these reports patient's benefit is achieved when the mean postoperative air-conduction threshold (for the range of 0.5 to 4 kHz) in the operated ear is at most 30 dB HL. In these studies hearing in the contralateral ear varies from normal to severely impaired.

The cut-off level of 30 dB HL for social acceptable hearing can not be confirmed by the results of our study. Although not very strong, audiometric improvement of hearing and increase of the psychometric (m)AIAD-score are significantly related. However, the average psychometric (m)AIAD-score is almost independent of postoperative hearing loss between 25 and 40 dB HL. A clear correlation exists between the average (m)AIAD-score and postoperative audiometric hearing levels of less than 25 dB HL and more than 40 dB HL. Patient's benefit seems related to the magnitude of improvement in the air-conduction thresholds, rather than to the achievement of a certain threshold level. In addition, even small residual hearing losses (less than 30 dB HL) still lead, on average, to (m)AIAD-scores that are substantially lower than the scores for normal hearing subjects.

An individual approach instead of the rigid implementation of audiometric parameters is not only preferable in reconstructive middle ear surgery and other rehabilitation procedures, but also for employment and related medico-legal purposes.

SAMENVATTING

In dit proefschrift worden enkele relevante en actuele aspecten van de reconstructieve middenoorchirurgie nader bestudeerd. Of een reconstructieve middenoorchirurgie daadwerkelijk tot succes leidt, of juist gedoemd is te mislukken, wordt in het algemeen bepaald door twee factoren: het technische en het functionele aspect van de reconstructieve middenoorchirurgie.
Tot het technische aspect van de reconstructieve middenoorchirurgie behoren de ontwikkeling van de microchirurgische technieken, het onderkennen van het belang van de functie van de buis van Eustachius, de steeds verbeterende inzichten en technieken met betrekking tot de reconstructie van het trommelvlies en de gehoorbeentjesketen en de introductie van biomaterialen voor implantatiedoeleinden.
Het functionele aspect van de reconstructieve middenoorchirurgie betreft de subjectieve gehoorkwaliteit na de gehoorherstellende operatie. De individuele gehoorkwaliteit kan worden omschreven als de beperking (disability) en/of handicap die een persoon ervaart als gevolg van zijn of haar (resterende) gehoorverlies. Inzichten in de subjectieve gehoorkwaliteit zijn niet alleen van belang met betrekking tot gehoorverbeterende chirurgie en revalidatie, maar kunnen ook een belangrijke rol spelen in medicolegale zaken.
In de eerste helft van dit proefschrift worden de resultaten gerapporteerd van onderzoekingen die zich specifiek richten op een deelgebied van het technische aspect van de reconstructieve middenoorchirurgie: de biocompatibiliteit van de synthetische middenoorimplantaten.
In het tweede deel van het proefschrift worden studieresultaten beschreven die het functionele aspect van de reconstructieve middenoorchirurgie betreffen.

In hoofdstuk 2 wordt een literatuuroverzicht beschreven met betrekking tot de technische en functionele aspecten van de reconstructieve oorchirurgie. In het eerste gedeelte van het overzicht worden voortschrijdende inzichten betreffende de middenoormechanica en de biocompatibiliteit van de voor implantatie gebruikte materialen beschreven. In het tweede gedeelte van het overzicht wordt een kritische beschouwing gegeven over de psychometrische mogelijkheden om de subjectieve gehoorkwaliteit vast te stellen.

Het technische aspect van de reconstructieve middenoorchirurgie

Slechthorendheid wordt vrijwel altijd veroorzaakt door een disfunctie van middenoor of binnenoor. Aan middenoorslechthorendheid (geleidingsverlies) ligt veelal een defect van de gehoorbeentjesketen ten grondslag. Een dergelijke beschadiging

kan worden veroorzaakt door een chronisch ontstekingsproces, cholesteatoom of trauma, of kan het gevolg zijn van een aangeboren afwijking. Een gedestrueerde gehoorbeentjesketen kan vervangen worden door een transplantaat of implantaat. Vanwege de kans op reintroductie van chronische ontsteking of cholesteatoom via een autogeen transplantaat en overdracht van "slow-virus" ziekten (bijvoorbeeld de ziekte van Creutzfeldt-Jacob en AIDS) via een allogeen transplantaat wordt in toenemende mate de voorkeur gegeven aan het gebruik van synthetische biomaterialen voor de reconstructie van de gehoorbeentjesketen.

In Hoofdstuk 3 worden de resultaten beschreven van een prospectieve dierexperimentele studie, waarin de biocompatibiliteit van synthetische middenoorprotheses nader wordt onderzocht. In de beginperiode van ketenreconstructie met synthetische implantaten werden hoge extrusiepercentages waargenomen, als gevolg van een vreemdlichaamreactie gericht tegen het implantatiemateriaal. Met de introductie van hoogwaardige biocompatibele keramische materialen, waartoe bijvoorbeeld hydroxylapatiet behoort, is het extrusiepercentage aanzienlijk verlaagd. Ondanks de biocompatibiliteit van de gebruikte keramische materialen blijft het risico op extrusie van het implantaat aanwezig, indien er direct contact bestaat tussen het implantaat en het trommelvlies. In deze gevallen wordt extrusie hoogst waarschijnlijk niet veroorzaakt door een vreemdlichaamreactie tegen het implantaat, maar is de uitstoting waarschijnlijk het gevolg van druknecrose van het trommelvlies.
In deze studie werd bij cavia`s een kraakbeenschijfje geplaatst tussen een synthetisch middenoorimplantaat en het trommelvlies, om het effect op het extrusieproces van het implantaat te onderzoeken. In de experimentele groep werd een kraakbeenschijfje geplaatst tussen de kop van de middenoorprothese van hydroxylapatiet en het trommelvlies; in de controlegroep werd de middenoorprothese in direct contact gebracht met het trommelvlies. De histopathologische aspecten van het trommelvlies als gevolg van het protrusie- en extrusieproces van de middenoorimplantaten werden bestudeerd door middel van lichtmicroscopische en transmissie en elektronenmicroscopische technieken. In dit experimentele model werd zowel protrusie als extrusie van middenoorprotheses van hydroxylapatiet grotendeels voorkomen door interpositie van een kraakbeenschijfje.

In Hoofdstuk 4 wordt het Groningen Cartilage Cutting Device geïntroduceerd: een nieuw instrument voor de reconstructieve middenoorchirurgie. Al jaren worden biocompatibele synthetische materialen succesvol door otologische chirurgen gebruikt voor de reconstructie van de gehoorbeentjesketen met de daarbij horende problemen zoals rejectie en extrusie. In Hoofdstuk 3 is beschreven dat de kans op extrusie aanzienlijk gereduceerd kan worden door interpositie van een kraakbeenschijfje tussen een synthetische middenoorprothese en het trommelvlies. De trillingsoverdracht van

geluid kan echter door kraakbeeninterpositie beïnvloed worden indien dit schijfje te dik is. Is daarentegen het kraakbeenschijfje te dun, dan blijft de kans op extrusie verhoogd aanwezig.
We beschrijven in dit hoofdstuk een gestandaardiseerde methode om een kraakbeenschijfje te verkrijgen dat voldoet aan de geformuleerde doelstellingen.

In Hoofdstuk 5 wordt de biocompatibiliteit van uit hydroxylapatiet-polyethyleen samengestelde middenoorimplantaten (HAPEX, Entermed) onderzocht. Momenteel wordt het grootste deel van de synthetische middenoorprotheses vervaardigd van hydroxylapatiet wegens de hoogwaardige biocompatibele eigenschappen. Deze protheses worden in de middenoorholte na korte tijd bedekt door epitheel en een fibreus laagje, zonder dat er aanwijzingen zijn voor een vreemdlichaamreactie. Middenoorimplantaten van hydroxylapatiet hebben een nadeel: ze zijn peroperatief moeilijk te bewerken, omdat ze gemakkelijk versplinteren bij het op maat snijden van de schacht. Daarom is polyethyleen aan de schacht toegevoegd. Polyethyleen kan peroperatief gemakkelijk geremodelleerd worden en het gedraagt zich als een biocompatibel materiaal, behalve wanneer het in contact is met het trommelvlies. Om de biocompatibiliteit te combineren met goede manipuleerbaarheid werd door de fabrikant een materiaal vervaardigd dat voor 40% uit hydroxylapatiet en voor 60% uit polyethyleen bestaat. Dit samengestelde materiaal kan met een mesje op lengte worden gesneden zonder kans op versplintering. HAPEX-middenoorprotheses bestaan uit een kop van hydroxylapatiet en uit een schacht die is samengesteld uit 40% hydroxylapatiet en 60% polyethyleen.
In deze studie werden elf HAPEX-middenoorprotheses tijdens revisiechirurgie verwijderd en vervolgens bestudeerd met behulp van lichtmicroscopie alsmede transmissie en scanning elektronenmicroscopie. Uit het microscopische onderzoek bleek, dat de protheses bedekt worden met fibreus weefsel, met daarover een dun laagje epitheel. Er werden in deze studie geen aanwijzingen gevonden voor de aanwezigheid van macrofagen of vreemdlichaam-reuscellen, die geassocieerd worden met een vreemdlichaamreactie tegen het materiaal. Hydroxylapatiet-polyethyleen- implantaten (HAPEX, Entermed) worden daarom zeer geschikt bevonden voor toepassing in de reconstructieve middenoorchirurgie.

Het functionele aspect van de reconstructieve middenoorchirurgie

Uitgangspunt van de reconstructieve middenoorchirurgie is een optimaal herstel van het gehoor na een beschadiging van de gehoorbeentjesketen. In de otologische literatuur worden twee methoden beschreven (de"Rule of Thumb"en de "Glasgow Benefit Plot") die een voorspellende waarde zouden hebben met betrekking tot het te verwachten resultaat van middenoorreconstructies die verbetering van het gehoor

als primaire doel hebben. Deze twee methoden zijn gebaseerd op het concept dat het individuele oor pas een bijdrage levert aan het horen als de gevoeligheid van dit oor beter is dan een bepaalde kritische waarde. Deze waarde wordt vaak gedefinieerd als 30 dB HL en wordt ook wel de grens voor een sociaal acceptabel gehoor genoemd. Functioneert het individuele oor beneden deze kritische grens dan zou dit oor functioneel geen bijdrage leveren aan het horen en wordt de hoorcapaciteit alleen bepaald door de bijdrage van het andere (contralaterale) oor. De kritische grens van 30 dB HL is echter vrij arbitrair gekozen en dient derhalve gevalideerd te worden.

In Hoofdstuk 6 worden voorlopige studieresultaten beschreven, die een indruk geven van de kwaliteit van het gehoor van een patiënt, nadat deze een reconstructieve middenooroperatie heeft ondergaan. Het gehoor wordt in deze studie onderzocht met behulp van een beknopte vragenlijst, die de beperkingen meet van het gehoor in het dagelijks leven, ter aanvulling op toonaudiometrie, waarbij de gehoordrempels worden gemeten (in dB HL). In deze studie wordt een relatie aangetoond tussen de mate van het subjectieve gehoorverlies (gemeten met behulp van de vragenlijst) en het gehoorverlies uitgedrukt in luchtgeleidingsdrempels. Op basis van de resultaten werd geconcludeerd dat nadere validering van de waarde van 30 dB HL als bovengrens voor een sociaal acceptabel gehoor door middel van een grotere prospectieve studie wenselijk is .

In Hoofdstuk 7 wordt de psychometrische geschiktheid van de (gemodificeerde) Amsterdam Inventory for Auditory Disability and Handicap ((m)AIAD) onderzocht. De (m)AIAD is een vragenlijst specifiek gericht op de invloed van slechthorendheid op het functioneren in het dagelijks leven. In deze studie zijn 94 personen geïncludeerd, met een leeftijd van 17 tot 65 jaar. Op twee verschillende tijdstippen (met exact een maand ertussen) werd de (m)AIAD ingevuld en werden tevens gehoordrempelmetingen verricht. Om de scores op de (m)AIAD te kunnen correleren met scores op een reeds gevalideerde vragenlijst, werd op beide tijdstippen een tweede vragenlijst ingevuld, namelijk de Hearing Disability Questionaire (HDQ). De psychometrische geschiktheid van de (m)AIAD is getest door het bepalen van betrouwbaarheid en validiteit. Betrouwbaarheid werd getest door het berekenen van de interne-consistentie, de "split-half" correlatie en "test-retest- reproduceerbaarheid. De validiteit werd getest aan de hand van "construct"- en "criterion"validiteit. De betrouwbaarheid blijkt ruim voldoende te zijn en de constructvaliditeit laat een hoge correlatie zien tussen scores op de (m)AIAD en de HDQ. Criterionvaliditeit laat een matige, maar significante, correlatie zien tussen scores op de (m)AIAD en gehoordrempels in dB HL. Deze matige correlatie tussen scores op de (m)AIAD en de gehoordrempels wordt niet veroorzaakt door een inadequate manier van invullen van de vragenlijsten, maar illustreert de zwakke relatie tussen audiometrische gegevens en de subjectieve

beleving van het gehoor (gemeten middels vragenlijsten). De gehoorbeperking die een persoon ervaart als gevolg van zijn of haar gehoorverlies wordt niet duidelijk voorspeld door het audiogram alleen. De validiteits- en betrouwbaarheidsresultaten voor de (m)AIAD zijn in overeenstemming met de resultaten die in de literatuur gevonden kunnen worden voor andere (robuust bevonden) vragenlijsten.
Geconcludeerd kan worden dat de (m)AIAD geschikt is om de invloed van een eventueel gehoorverlies op het dagelijks leven te meten.

In Hoofdstuk 8 worden de resultaten beschreven die zijn verkregen bij gebruik van de (m)AIAD om een verandering van het gehoor te meten na een medische ingreep. Het onderzoek is uitgevoerd in de vorm van een prospectieve studie, waarin 66 patiënten een reconstructieve middenooroperatie ondergingen. Preoperatief en postoperatief werden gehoordrempels bepaald, en werd tevens het gehoor gemeten middels de (m)AIAD.
Voor de (m)AIAD werd een test-retest correlatie gemeten van 0.85. Hoewel dit een tamelijk hoge waarde is betekent dit dat een individuele score op de (m)AIAD ook zonder interventie verandert. Voor de interpretatie van de resultaten is daarom het bepalen van het interval voor "true change" van belang. Voor de correlatie tussen het verschil in gehoordrempels voor en na de ingreep en het verschil in scores op de (m)AIAD werd een waarde van 0.35 gevonden (Pearson's r). Verdere statische analyses tonen aan dat de totaalscore op de (m)AIAD met minimaal 16 punten moet veranderen wil de verandering als een "true change" beschouwd worden. Van de 66 patiënten voldoen maar 9 patiënten aan dit criterium. Deze studie laat zien dat een vragenlijst ondanks adequate psychometrische eigenschappen (gemeten middels validiteit en betrouwbaarheid) beperkingen heeft, wanneer de lijst wordt gebruikt om het resultaat van medische interventie in een individuele patiënt te meten.

In Hoofdstuk 9 wordt de relatie beschreven tussen audiometrische en psychometrische metingen van het gehoor na reconstructieve middenoorchirurgie. Dit met het uiteindelijke doel criteria te kunnen definiëren voor preoperatieve selectie van patiënten voor reconstructieve middenoorchirurgie, primair ter verbetering van het gehoor. Over deze criteria bestaat tussen de verschillende medische instituten (nog) geen consensus. Ook zijn deze criteria vaak gebaseerd op de arbitraire grens van 30 dB voor een sociaal acceptabel gehoor.
In deze studie werd het gehoor gemeten middels toondrempelaudiometrie (in dB HL) en de (m)AIAD. Preoperatief en 12 maanden postoperatief werden de gemiddelde gehoordrempels en de (m)AIAD-scores geëvalueerd voor 80 patiënten.
De luchtgeleidingsdrempel van het geopereerde oor is gemiddeld verbeterd met 5.4 (14.3) dB, de gemiddelde verbetering in (m)AIAD-score is 2.9 (12.1) punten.

De gevonden relatie tussen audiometrische verbetering en toename in score op de (m)AIAD is niet sterk, maar is wel significant.
Ook werden de data gegroepeerd in verschillende 10 dB-intervallen, waarna de relatie tussen postoperatief gehoorverlies (gemiddeld over twee oren) en de gemiddelde postoperatieve (m)AIAD-score opnieuw werd bepaald. Dit leverde een opvallende relatie op: de (m)AIAD-score is bijna onafhankelijk van het gehoorverlies voor postoperatieve gehoordrempels tussen de 25 en 40 dB. Het persisterende postoperatieve gehoorverlies moet kleiner zijn dan 25 dB, wil een vermindering in gehoorverlies samenhangen met een verbetering in (m)AIAD-score. Zijn de gehoorverliezen groter dan 40 dB, dan is er een duidelijke relatie te zien tussen toename van het gehoorverlies en verslechtering van de (m)AIAD-score. Wat in deze studie ook duidelijk naar voren komt is dat kleine persisterende gehoorverliezen in het algemeen genomen ook tot (m)AIAD-scores leiden die beduidend slechter zijn dan de scores voor normaal horende personen.

Conclusies

Technisch aspect van de reconstructieve middenoorchirurgie

Protrusie en extrusie van middenoorprotheses van hydroxylapatiet wordt (bij cavia's) grotendeels voorkomen indien een kraakbeenschijfje wordt geplaatst tussen het trommelvlies en de kop van de prothese.
Gebruik van het Groningen Cartilage Cutting Device levert een significante bijdrage aan de reconstructieve middenoorchirurgie omdat daarmee een standaard kraakbeenschijfje kan worden verkregen, dat voldoet aan de kritische mechanische voorwaarden.
Middenoorprotheses samengesteld uit hydroxylapatiet en polyethyleen (HAPEX, Entermed) tonen een goede biocompatibiliteit na positionering tussen het trommelvlies en de stapes of stapesvoetplaat. Er bestaan geen aanwijzingen voor een mogelijke vreemdlichaamreactie tegen het prothesemateriaal, gezien de afwezigheid van macrofagen of vreemdlichaam-reuscellen.

Functioneel aspect van de reconstructieve middenoorchirurgie

In de otologische literatuur wordt als grens voor een sociaal acceptabel gehoor vaak een maximale waarde voor het gehoorverlies van 30 dB gehanteerd. Deze grens is gebaseerd op de resultaten van een tweetal studies die een voorspellende waarde zouden hebben met betrekking tot de indicatiestelling voor middenoorreconstruc-

ties (de "Rule of Thumb" en de "Glasgow Benefit Plot"). Volgens de uitkomsten van deze studies moet na een gehoorverbeterende operatie de gemiddelde luchtgeleidingsdrempel (voor 0.5 tot 4 kHz) van het geopereerde oor kleiner zijn dan of gelijk zijn aan 30 dB, wil een patiënt subjectief een gehoorverbetering ervaren. In beide studies kan het niet-geopereerde oor normaal tot ernstig slechthorend zijn.
Een grens van 30 dB HL voor sociaal acceptabel gehoor wordt niet bevestigd door de resultaten van onze studie. Ook al is de relatie niet erg sterk, verbetering van de gehoordrempel en verbetering van de psychometrische (m)AIAD-score zijn significant gecorreleerd. Echter, de gemiddelde (m)AIAD-score is bijna onafhankelijk van het gehoorverlies voor postoperatieve gehoordrempels tussen de 25 en 40 dB. Wel is er een duidelijke correlatie tussen (m)AIAD-score en postoperatieve gehoorverliezen als het persisterende postoperatieve gehoorverlies kleiner is dan 25 dB of groter dan 40 dB. De door een patiënt ervaren verbetering lijkt eerder gerelateerd aan de mate van verbetering in luchtgeleidingsdrempels, dan aan het behalen van een bepaalde kritische grens. Wat in deze studie ook duidelijk naar voren komt is dat kleine persisterende gehoorverliezen in het algemeen genomen ook tot (m)AIAD-scores leiden die beduidend slechter zijn dan de scores voor normaal horende personen.
Een individuele benadering in plaats van de rigide toepassing van audiometrische parameters, is niet alleen te verkiezen in de reconstructieve middenoorchirurgie, maar is ook van belang voor revalidatiedoeleinden en medico-legale zaken.

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Curriculum vitae

Astrid GW Meijer werd op 30 november 1967 geboren te Wageningen. Na het behalen van het eindexamen VWO-Atheneum (ongedeeld) aan het Lambert Frankens College te Elburg begon zij in 1987 met de studie geneeskunde aan de Rijksuniversiteit te Groningen. Het artsexamen werd behaald in 1996. In april 1996 begon zij als arts-assistent op de afdeling KNO in het Academisch Ziekenhuis Groningen. Vanaf 15 februari 1998 is zij in opleiding tot Keel-, Neus- en Oorarts in het Academisch Ziekenhuis Groningen, half februari 2003 hoopt zij haar opleiding tot KNO-arts met goed gevolg af te ronden. Nadien zal zij participeren in de medische staf van deze kliniek.
De auteur is getrouwd met Jac HWM Korsten en samen hebben zijn een zoon: Matthijs.

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